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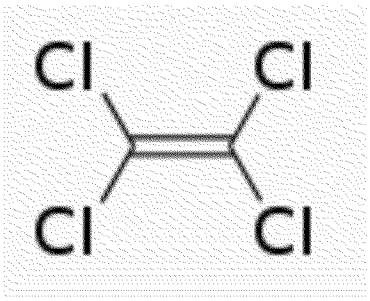
Office of Chemical Safety and
Pollution Prevention

United States
Environmental Protection Agency

# Scope of the Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro)

## CASRN: 127-18-4

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**Docket**

Supporting information can be found in public docket: EPA-HQ-OPPT-2016-0732

**Disclaimer**

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# ABBREVIATIONS

| | |
|---|---|
| °C | Degrees Celsius |
| 1-BP | 1-Bromopropane |
| ACGIH | American Conference of Government Industrial Hygienists |
| AEGL | Acute Exposure Guideline Level |
| ATSDR | Agency for Toxic Substances and Disease Registries |
| atm | Atmosphere(s) |
| BAF | Bioaccumulation Factor |
| BCF | Bioconcentration Factor |
| CAA | Clean Air Act |
| CASRN | Chemical Abstracts Service Registry Number |
| CBI | Confidential Business Information |
| $CCL_4$ | Carbon Tetrachloride |
| CDC | Centers for Disease Control |
| CDR | Chemical Data Reporting |
| CEHD | Chemical Exposure Health Data |
| CEPA | Canadian List of Toxic Substances |
| CERCLA | Comprehensive Environmental Response, Compensation and Liability Act |
| CFC | Chlorofluorocarbon |
| CHIRP | Chemical Risk Information Platform |
| $cm^3$ | Cubic Centimeter(s) |
| COC | Concentration of Concern |
| CoRAP | Community Rolling Action Plan |
| cP | Centipoise |
| CPCat | Chemical and Product Categories |
| CPSC | Consumer Product Safety Commission |
| CSCL | Chemical Substances Control Law |
| CWA | Clean Water Act |
| DNAPL | Dense Non-Aqueous Phase Liquid |
| ECHA | European Chemicals Agency |
| EDC | Ethylene Dichloride |
| EG | Effluent Guidelines |
| EPA | Environmental Protection Agency |
| EPCRA | Emergency Planning and Community Right-to-Know Act |
| ESD | Emission Scenario Documents |
| EU | European Union |
| FDA | Food and Drug Administration |
| FFDCA | Federal Food, Drug and Cosmetic Act |
| FHSA | Federal Hazardous Substance Act |
| FIFRA | Federal Insecticide, Fungicide and Rodenticide Act |
| g | Gram(s) |
| GACT | Generally Available Control Technology |
| HAP | Hazardous Air Pollutant |
| HCFC | Hydrochlorofluorocarbon |
| HCl | Hydrochloric Acid |
| HFC | Hydrofluorocarbon |

| | |
|---|---|
| HSIA | Halogenated Solvents Industry Association |
| HPV | High Production Volume |
| IARC | International Agency for Research on Cancer |
| IDLH | Immediately Dangerous to Life and Health |
| i.p. | Intraperitoneal |
| IRIS | Integrated Risk Information System |
| ISHA | Industrial Safety and Health Act |
| kg | Kilogram(s) |
| L | Liter(s) |
| lb | Pound |
| Log $K_{oc}$ | Logarithmic Organic Carbon:Water Partition Coefficient |
| Log $K_{ow}$ | Logarithmic Octanol:Water Partition Coefficient |
| $m^3$ | Cubic Meter(s) |
| MACT | Maximum Achievable Control Technology |
| MCL | Maximum Contaminant Level |
| MCLG | Maximum Contaminant Level Goal |
| mg | Milligram(s) |
| µg | Microgram(s) |
| mmHg | Millimeter(s) of Mercury |
| MOA | Mode of Action |
| MSDS | Material Safety Data Sheet |
| n | Number |
| NAAQS | National Ambient Air Quality Standards |
| NAC | National Advisory Committee |
| NAICS | North American Industry Classification System |
| NCEA | National Center for Environmental Assessment |
| NEI | National Emissions Inventory |
| NESHAP | National Emission Standards for Hazardous Air Pollutants |
| NHANES | National Health and Nutrition Examination Survey |
| NICNAS | National Industrial Chemicals Notification and Assessment Scheme |
| NIH | National Institutes of Health |
| NIOSH | National Institute of Occupational Safety and Health |
| NITE | National Institute of Technology and Evaluation |
| NPL | National Priorities List |
| NTP | National Toxicology Program |
| OAQPS | Office of Air Quality Planning and Standards |
| OCSPP | Office of Chemical Safety and Pollution Prevention |
| ODS | Ozone Depleting Substance |
| OECD | Organisation for Economic Co-operation and Development |
| OEHHA | Office of Environmental Health Hazard Assessment |
| OEL | Occupational Exposure Limit |
| OPPT | Office of Pollution Prevention and Toxics |
| OSHA | Occupational Safety and Health Administration |
| OW | Office of Water |
| PCE | Perchloroethylene |
| PEL | Permissible Exposure Limit |

| | |
|---|---|
| POD | Point of Departure |
| POTW | Publicly Owned Treatment Works |
| ppm | Part(s) per Million |
| PWS | Public Water System |
| RCRA | Resource Conservation and Recovery Act |
| SARA | Superfund Amendments and Reauthorization Act |
| SCHER | Scientific Committee on Health and Environmental Risks |
| SDS | Safety Data Sheet |
| SDWA | Safe Drinking Water Act |
| SNAP | Significant New Alternatives Policy |
| STEL | Short-Term Exposure Limit |
| $t_{1/2}$ | Half-life |
| TCCR | Transparent, Clear, Consistent, and Reasonable |
| TCE | Trichloroethylene |
| TLV | Threshold Limit Value |
| TRI | Toxics Release Inventory |
| TSCA | Toxic Substances Control Act |
| TTO | Total Toxic Organics |
| TWA | Time-Weighted Average |
| U.S. | United States |
| VOC | Volatile Organic Compound |
| WHO | World Health Organization |

# EXECUTIVE SUMMARY

TSCA § 6(b)(4) requires U.S. Environmental Protection Agency (EPA) to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use." In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). Perchloroethylene was one of these chemicals.

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. This document fulfills the TSCA § 6(b)(4)(D) requirement for perchloroethylene.

This document presents the scope of the risk evaluation to be conducted for perchloroethylene. If a hazard, exposure, condition of use or potentially exposed or susceptible subpopulation has not been discussed, EPA, at this point in time, is not intending to include it in the scope of the risk evaluation. As per the rulemaking, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)*, with respect to conditions of use in conducting a risk evaluation under TSCA, EPA will first identify "circumstances" that constitute "conditions of use" for each chemical. While EPA interprets this as largely a factual determination—i.e., EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion.

To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. Time constraints have resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be.

Because there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents, EPA will publish and take public comment on a problem formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluation for perchloroethylene. This problem formulation is expected to be released within approximately 6 months of publication of the scope.

Perchloroethylene, also known as ethene, 1,1,2,2-tetrachloro, tetrachloroethylene and PCE, is a high production volume (HPV) solvent [see *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Tetrachloroethylene (Perchloroethylene)*, EPA-HQ-OPPT-2016-0732-0003]. Perchloroethylene is subject to a number of federal and state regulations and reporting requirements. For example, perchloroethylene has been a Toxics Release Inventory (TRI) reportable chemical under Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) since 1995. It is designated a Hazardous Air Pollutant (HAP) under the Clean Air Act (CAA), a hazardous waste under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and a regulated drinking water contaminant under the Safe Drinking Water Act (SDWA).

Information on the domestic manufacture, processing and use of perchloroethylene is available to EPA through its Chemical Data Reporting (CDR) Rule, issued under TSCA. According to the 2016 CDR, more than 324 million pounds of perchloroethylene were manufactured (including imported) in the United States in 2015. According to the *Use and Market Profile for Tetrachloroethylene* (EPA-HQ-OPPT-2016-0732), perchloroethylene is primarily used to produce fluorinated compounds, such as hydrofluorocarbons (HFCs) and hydrochlorofluorocarbons (HCFCs) (65%) followed by dry cleaning (15%) and vapor degreasing solvents (10%). Other uses can be quite varied, including:

- Adhesives
- Degreasing
- Brake cleaner
- Laboratories
- Lubricants
- Mold cleaners, releases and protectants
- Oil refining
- Sealants
- Stainless steel polish
- Tire buffers and cleaners and
- Vandal mark removers.

The initial conceptual models presented in Section 2 identify conditions of use; exposure pathways (e.g., media); exposure routes (e.g., inhalation, dermal, oral); potentially exposed populations, including potentially exposed or susceptible subpopulations; and hazards EPA expects to evaluate based on the inherent hazards of the chemical.

This document presents the occupational scenarios in which workers and occupational non-users may be exposed to perchloroethylene during a variety of conditions of use, such as manufacturing, processing and uses in dry cleaning, adhesives and degreasing. EPA expects that the highest exposures to perchloroethylene generally involve workers in industrial and commercial settings. Perchloroethylene can be found in numerous commercial and consumer products, resulting in exposures to commercial workers and consumers. The consumer conceptual model indicates exposures occurring from perchloroethylene-containing products in either indoor or outdoor environments. For perchloroethylene, EPA believes that workers, consumers, and bystanders as well as certain other groups of individuals may experience greater exposures than the general population. EPA will evaluate whether other groups of individuals within the general population may be exposed via pathways that are distinct from the general population due to unique characteristics (e.g., life stage, behaviors, activities, duration), or have greater susceptibility than the general population, and should therefore be considered relevant potentially exposed or susceptible subpopulations for purposes of this risk evaluation.

Exposures to the general population may occur from industrial releases. The Toxics Release Inventory identifies releases of perchloroethylene to air, water and land, with the majority being releases to air. The general population can be exposed to perchloroethylene through inhalation, oral and dermal pathways due to its widespread presence in a variety of environmental media such as in air, drinking water, ground water and/or surface water. EPA considers workers, occupational nonusers, consumers and bystanders and certain groups of individuals who may experience greater exposures due to proximity to conditions of use, as potentially exposed or susceptible subpopulations.

Perchloroethylene has been the subject of numerous health hazard and risk assessments, based on human and animal data. Any existing assessments will be a starting point as EPA will conduct a systematic review of the literature, including new literature since the existing assessments, as available in *Perchloroethylene (CASRN 127-18-4) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0732). EPA expects to consider hazards identified in the recent assessment by the EPA Integrated Risk Information System (IRIS) Program: neurotoxicity, kidney toxicity, liver toxicity, developmental and reproductive toxicity and cancer. Support for an association with immune and blood effects was less well characterized. Perchloroethylene is also considered to be irritating.

The initial analysis plan describes EPA's plan for conducting systematic review of readily available information and identification of assessment approaches to be used in conducting the risk evaluation for perchloroethylene. The initial analysis plan will be used to develop the problem formulation and final analysis plan for the risk evaluation of perchloroethylene.

# 1 INTRODUCTION

This document presents the scope of the risk evaluation to be conducted for perchloroethylene. If a condition of use has not been discussed, EPA, at this point in time, is not intending to include that condition of use in the scope of the risk evaluation. Moreover, during problem formulation EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation. Any condition of use that will not be evaluated will be clearly described in the problem formulation document.

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended the Toxic Substances Control Act (TSCA), the nation's primary chemicals management law, was signed into law. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

TSCA § 6(b)(4) requires the U.S. Environmental Protection Agency (EPA) to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use."

In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). These 10 chemical substances were drawn from the 2014 update of EPA's TSCA Work Plan for Chemical Assessments, a list of chemicals that EPA identified in 2012 and updated in 2014 (currently totaling 90 chemicals) for further assessment under TSCA. EPA's designation of the first 10 chemical substances constituted the initiation of the risk evaluation process for each of these chemical substances, pursuant to the requirements of TSCA § 6(b)(4).

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. On February 14, 2017, EPA convened a public meeting to receive input and information to assist the Agency in its efforts to establish the scope of the risk evaluations under development for the ten chemical substances designated in December 2016 for risk evaluations pursuant to TSCA. EPA provided the public an opportunity to identify information, via oral comment or by submission to a public docket, specifically related to the conditions of use for the ten chemical substances. EPA used this information in developing this scope document, which fulfills the TSCA § 6(b)(4)(D) requirement for perchloroethylene.

As per the rulemaking, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)*, in conducting a risk evaluation under TSCA EPA will first identify "circumstances" that constitute "conditions of use" for each chemical. While EPA interprets this as largely a factual determination—*i.e.*, EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion. Based on legislative history, statutory structure and other evidence of Congressional intent, EPA has determined that certain activities may not generally be considered to be conditions of use. In exercising its discretion, for example, EPA would not generally consider that a single

unsubstantiated or anecdotal statement (or even a few isolated statements) on the internet that a chemical can be used for a particular purpose would necessitate concluding that this represented part of the chemical substance's "conditions of use." As a further example, although the definition could be read literally to include all intentional misuses (e.g., inhalant abuse), as a "known" or "reasonably foreseen" activity in some circumstances, EPA does not generally intend to include such activities in either a chemical substance's prioritization or risk evaluation. In addition, EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context. For instance, the conditions of use for purposes of section 6 might reasonably include the use of a chemical substance in insulation where the manufacture, processing or distribution in commerce for that use is prospective or on-going, but would not include the use of the chemical substance in previously installed insulation, if the manufacture, processing or distribution for that use is not prospective or on-going. In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle. That said, in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses.

Furthermore, in exercising its discretion under section 6(b)(4)(D) to identify the conditions of use that EPA expects to consider in a risk evaluation, EPA believes it is important for the Agency to have the discretion to make reasonable, technically sound scoping decisions in light of the overall objective of determining whether chemical substances in commerce present an unreasonable risk. Consequently, EPA may, on a case-by case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern meriting an unreasonable risk consideration. For example, EPA intends to exercise discretion in addressing circumstances where the chemical substance subject to scoping is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping, in order to determine which risk evaluation the potential risks from the chemical substance should be addressed in. As an additional example, EPA may, on a case-by-case basis, exclude uses that EPA has sufficient basis to conclude would present only "*de minimis*" exposures. This could include uses that occur in a closed system that effectively precludes exposure or use as an intermediate. During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks.

The situations identified above are examples of the kinds of discretion that EPA will exercise in determining what activities constitute conditions of use, and what conditions of use are to be included in the scope of any given risk evaluation. See the preamble to *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)* for further discussion of these issues.

To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. The first 10 chemical substances were not subject to the prioritization process that will be used in the future in

accordance with amendments to TSCA. EPA expects to collect and screen much of the relevant information about chemical substances that will be subject to the risk evaluation process during and before prioritization. The volume of data and information about the first 10 chemicals that is available to EPA is extremely large and EPA is still in the process of reviewing it, since the Agency had limited ability to process the information gathered before issuing the scope documents for the first 10 chemicals. As a result of the statutory timeframes, EPA had limited time to process all of the information gathered during scoping for the first 10 chemicals within the time provided in the statute for publication of the scopes after initiation of the risk evaluation process. For these reasons, EPA's initial screenings and designations with regard to applicability of data (e.g., on-topic vs. off-topic information and data) may change as EPA progresses through the risk evaluation process. Likewise, the Conceptual Models and Analysis Plans provided in the first 10 chemical scopes are designated as "Initial" to indicate that EPA expects to further refine them during problem formulation.

The aforementioned time constraints have resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be. In addition, there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents. For these reasons, EPA will publish and take public comment on a problem formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluations for the first 10 chemicals. This problem formulation is expected to be released within approximately 6 months of publication of the scope.

## 1.1 Regulatory History

EPA conducted a search of existing domestic and international laws, regulations and assessments pertaining to perchloroethylene. EPA compiled this summary from data available from federal, state, international and other government sources, as cited in Appendix A. During risk evaluation, EPA will evaluate and consider the impact of these existing laws and regulations in the problem formulation step to determine what, if any further analysis might be necessary as part of the risk evaluation.

***Federal Laws and Regulations***

Perchloroethylene is subject to federal statutes or regulations, other than TSCA, that are implemented by other offices within EPA and/or other federal agencies/departments. A summary of federal laws, regulations and implementing authorities is provided in Appendix A.1.

***State Laws and Regulations***

Perchloroethylene is subject to state statutes or regulations implemented by state agencies or departments. A summary of state laws, regulations and implementing authorities is provided in Appendix A.2.

***Laws and Regulations in Other Countries and International Treaties or Agreements***

Perchloroethylene is subject to statutes or regulations in countries other than the United States. A summary of these laws and regulations is provided in Appendix A.3.

## 1.2 Assessment History

EPA has identified assessments conducted by other EPA Programs and other organizations (see Table 1-1). Depending on the source, these assessments may include information on conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations—information useful to EPA

in preparing this scope for risk evaluation. Table 1-1 shows the assessments that have been conducted. In addition to using this information, EPA intends to conduct a full review of the data collected see *Perchloroethylene (CASRN 127-18-4) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0732), using the literature search strategy [see *Strategy for Conducting Literature Searches for Perchloroethylene: Supplemental File for the TSCA Scope Document,* (EPA-HQ-OPPT-2016-0732)] to ensure that EPA is considering information that has been made available since these assessments were conducted.

**Table 1-1. Assessment History of Perchloroethylene**

| Authoring Organization | Assessment |
|---|---|
| **EPA Assessments** | |
| Integrated Risk Information System (IRIS) | Toxicological Review of Tetrachloroethylene (Perchloroethylene) (CAS No. 127-18-4) (U.S. EPA, 2012b) |
| Office of Air Quality Planning and Standards (OAQPS) | Perchloroethylene Dry Cleaners Refined Human Health Risk Characterization (2005b) |
| National Center for Environmental Assessment (NCEA) | Sources, Emission and Exposure for Trichloroethylene (TCE) and Related Chemicals (2001) |
| Office of Air Toxics | Tetrachloroethylene (Perchloroethylene); 127-18-4 (2000b) |
| Office of Pesticides and Toxic Substances (now, Office of Chemical Safety and Pollution Prevention [OCSPP]) | Occupational Exposure and Environmental Release Assessment of Tetrachloroethylene (1985b) |
| Office of Water | Final Health Effects Criteria Document for Tetrachloroethylene (U.S. EPA, 1985a) |
| Office of Water (OW) | Ambient Water Quality Criteria for Tetrachloroethylene (U.S. EPA, 1980a) |
| **Other U.S.-Based Organizations** | |
| California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (OEHHA), Air Toxics Hot Spots Program | Perchloroethylene Inhalation Cancer Unit Risk Factor (2016) |
| Agency for Toxic Substances and Disease Registry (ATSDR) | Toxicological Profile for Tetrachloroethylene (PERC) (Draft) (2014) |
| National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL Committee) | Tetrachloroethylene (2009) |
| California Environmental Protection Agency, OEHHA, Pesticide and Environmental Toxicology Section | Public Health Goal for Tetrachloroethylene in Drinking Water (2001) |

| Authoring Organization | Assessment |
|---|---|
| National Toxicology Program (NTP) | Toxicology and Carcinogenesis Studies of Tetrachloroethylene (Perchloroethylene); (CAS No. 127-18-4) in F344/N Rats and B6C3F1 Mice (1986) |
| **International** | |
| International Agency for Research on Cancer (IARC) | IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Tetrachloroethylene (2014) |
| European Union (EU), Scientific Committee on Health and Environmental Risks (SCHER) | SCHER, Scientific Opinion on the Risk Assessment Report on Tetrachloroethylene, Human Health Part, CAS No.: 127-18-4, 12 (2008) |
| World Health Organization (WHO) | Concise International Chemical Assessment Document 68; Tetrachloroethylene (2006) |
| EU | EU Risk Assessment Report; Tetrachloroethylene, Part 1 - environment (2005) |
| National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Australia | Tetrachloroethylene; Priority Existing Chemical Assessment Report No. 15 (2001) |

## 1.3 Data and Information Collection

EPA/OPPT generally applies a process and workflow that includes: (1) data collection (2) data evaluation and (3) data integration of the scientific data used in risk assessments developed under TSCA. Scientific analysis is often iterative in nature as new knowledge is obtained. Hence, EPA/OPPT expects that multiple refinements regarding data collection will occur during the process of risk evaluation.

***Data Collection: Data Search***

EPA/OPPT conducted chemical-specific searches for data and information on: physical and chemical properties; environmental fate and transport; conditions of use information; environmental exposures, human exposures, including potentially exposed or susceptible subpopulations; ecological hazard, human health hazard, including potentially exposed or susceptible subpopulations.

EPA/OPPT designed its initial data search to be broad enough to capture a comprehensive set of sources containing data and/or information potentially relevant to the risk evaluation. Generally, the search was not limited by date and was conducted on a wide range of data sources, including but not limited to: peer-reviewed literature and gray literature (e.g., publicly-available industry reports, trade association resources, government reports). When available, EPA/OPPT relied on the search strategies from recent assessments, such as EPA Integrated Risk Information System (IRIS) assessments and the National Toxicology Program's (NTP) *Report on Carcinogens,* to identify relevant references and supplemented these searches to identify relevant information published after the end date of the previous search to capture more recent literature. *Strategy for Conducting Literature Searches for Perchloroethylene: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0732) provides details about the data sources and search terms that were used in the initial search.

***Data Collection: Data Screening***

Following the data search, references were screened and categorized using selection criteria outlined in the supplemental document: *Strategy for Conducting Literature Searches for Perchloroethylene: Supplemental File for the TSCA Scope Document.* Titles and abstracts were screened against the criteria as a first step with the goal of identifying a smaller subset of the relevant data to move into the subsequent data extraction and data evaluation steps. Prior to full-text review, EPA/OPPT anticipates refinements to the search and screening strategies, as informed by an evaluation of the performance of the initial title/abstract screening and categorization process.

The categorization scheme (or tagging structure) used for data screening varies by scientific discipline (i.e., physical and chemical properties; environmental fate and transport; chemical use/conditions of use information; human and environmental exposures, including potentially exposed or susceptible subpopulations identified by virtue of greater exposure; human health hazard, including potentially exposed or susceptible subpopulations identified by virtue of greater susceptibility; and ecological hazard), but within each data set, there are two broad categories or data tags: (1) o*n-topic* references or (2) *off-topic* references. *On-topic* references are those that may contain data and/or information relevant to the risk evaluation. O*ff-topic* references are those that do not appear to contain data or information relevant to the risk evaluation. The supplemental document: *Strategy for Conducting Literature Searches for Perchloroethylene: Supplemental File for the TSCA Scope Document* discusses the inclusion and exclusion criteria that EPA/OPPT used to categorize references as *on-topic* or *off-topic*.

Additional data screening using sub-categories (or sub-tags) was also performed to facilitate further sorting of data/information, for example, identifying references by source type (e.g., published peer-reviewed journal article, government report); data type (e.g., primary data, review article); human health hazard (e.g., liver toxicity, cancer, reproductive toxicity); or chemical-specific and use-specific data or information. These sub-categories are described in supplemental document: *Strategy for Conducting Literature Searches for Perchloroethylene: Supplemental File for the TSCA Scope Document* and will be used to organize the different streams of data during the stages of data evaluation and data integration steps of systematic review.

Results of the initial search and categorization can be found in the supplemental document *Perchloroethylene (CASRN 127-18-4) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0732). This document provides a comprehensive list (bibliography) of the sources of data identified by the initial search and the initial categorization for *on-topic* and *off-topic* references. Because systematic review is an iterative process, EPA/OPPT expects that some references may move from the *on-topic* to the *off-topic* categories, and vice versa. Moreover, targeted supplemental searches may also be conducted to address specific needs for the analysis phase (e.g., to locate specific data needed for modeling); hence, additional *on-topic* references not initially identified in the initial search may be identified as the systematic review process proceeds.

# 2 SCOPE OF THE EVALUATION

As required by TSCA, the scope of the risk evaluation identifies the conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations that the Administrator expects to consider. To communicate and visually convey the relationships between these components, EPA is including an initial life cycle diagram and initial conceptual models that describe the actual or potential relationships between perchloroethylene and human and ecological receptors. An initial analysis plan is also included which identifies, to the extent feasible, the approaches and methods that EPA may use to assess exposures, effects (hazards) and risks under the conditions of use of perchloroethylene. As noted previously, EPA intends to refine this analysis plan during the problem formulation phase of risk evaluation.

## 2.1 Physical and Chemical Properties

Physical-chemical properties influence the environmental behavior and the toxic properties of a chemical, thereby informing the potential conditions of use, exposure pathways and routes and hazards that EPA intends to consider. For scope development, EPA considered the measured or estimated physical-chemical properties set forth in Table 2-1.

**Table 2-1. Physical and Chemical Properties of Perchloroethylene**

| Property | Value[a] | References |
|---|---|---|
| Molecular formula | $C_2Cl_4$ | |
| Molecular weight | 165.833 | |
| Physical form | Colorless liquid; ether-like, mildly sweet odor | Lewis (2007); NIOSH (2005); U.S. Coast Guard (1984) |
| Melting point | -22.3°C | Lide (2007) |
| Boiling point | 121.3°C | Lide (2007) |
| Density | 1.623 g/cm$^3$ at 20°C | Lide (2007) |
| Vapor pressure | 18.5 mmHg at 25°C | Riddick et al. (1985) |
| Vapor density | 5.7 (relative to air) | Browning (1965) |
| Water solubility | 206 mg/L at 25°C | Horvath (1982) |
| Octanol:water partition coefficient ($K_{ow}$) | 3.40 | Hansch et al. (1995) |
| Henry's Law constant | 0.0177 atm-m$^3$/mole | Gossett (1987) |
| Flash point | Not applicable | (NFPA, 2010) |
| Autoflammability | Not readily available | |
| Viscosity | 0.839 cP @at 25°C | Hickman (2000) |
| Refractive index | 1.4775 | Lide (2007) |
| Dielectric constant | 0 D | |

[a] Measured unless otherwise noted.

## 2.2 Conditions of Use

TSCA § 3(4) defines the conditions of use as ''the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.''

### 2.2.1 Data and Information Sources

As the first step in preparing these scope documents, EPA identified, based on reasonably available information, the conditions of use for the subject chemicals. As further described in this document, EPA searched a number of available data sources (e.g., *Use and Market Profile for Tetrachloroethylene*, EPA-HQ-OPPT-2016-0732). Based on this search, EPA published a preliminary list of information and sources related to chemical conditions of use [see *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Tetrachloroethylene (Perchloroethylene) and Use*, EPA-HQ-OPPT-2016-0732] prior to a February 2017 public meeting on scoping efforts for risk evaluation convened to solicit comment and input from the public. EPA also convened meetings with companies, industry groups, chemical users and other stakeholders to aid in identifying conditions of use and verifying conditions of use identified by EPA. The information and input received from the public and stakeholder meetings has been incorporated into this scope document to the extent appropriate, as indicated in Table 2-3. Thus, EPA believes the manufacture, processing, distribution, use and disposal activities identified in these documents constitute the intended, known, and reasonably foreseen activities associated with the subject chemicals, based on reasonably available information. The documents do not, in most cases, specify whether activity under discussion is intended, known, or reasonably foreseen, in part due to the time constraints in preparing these documents.

### 2.2.2 Identification of Conditions of Use

As part of the scope, an initial life cycle diagram is provided (Figure 2-1) depicting the conditions of use that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, use (industrial, commercial, consumer, where distinguishable), distribution and disposal. The information is grouped according to Chemical Data Reporting (CDR) processing codes and use categories (including functional use codes for industrial uses and product categories for commercial and consumer uses), in combination with other data sources (e.g., published literature and consultation with stakeholders) to provide an overview of conditions of use. EPA notes that some subcategories may be grouped under multiple CDR categories.

For the purposes of this scope, CDR definitions were used. CDR use categories include the following: "industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed. "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services. "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use (U.S. EPA, 2016a).

To understand conditions of use relative to one another and associated potential exposures under those conditions of use, the life cycle diagram includes the production volume associated with each stage of the life cycle, as reported in the 2016 CDR (U.S. EPA, 2016b), when the volume was not claimed confidential business information (CBI). The 2016 CDR reporting data for perchloroethylene

are provided in Table 2-2 from EPA's CDR database (U.S. EPA, 2016b). As demonstrated in Table 2-2, production and importation of perchloroethylene has decreased since 2012.

**Table 2-2. Production Volume of Perchloroethylene in CDR Reporting Period (2012 to 2015) [a]**

| Reporting Year | 2012 | 2013 | 2014 | 2015 |
|---|---|---|---|---|
| Total Aggregate Production Volume (lbs) | 387,623,401 | 391,403,540 | 355,305,850 | 324,240,744 |

[a] The CDR data for the 2016 reporting period is available via ChemView (https://java.epa.gov/chemview) (U.S. EPA, 2016b). Because of an ongoing CBI substantiation process required by amended TSCA, the CDR data available in the scope document is more specific than currently in ChemView.

Figure 2-1 depicts the initial life cycle diagram of perchloroethylene from manufacture to the point of disposal. EPA identified the use categories by reviewing the industrial processing use activities, and commercial and consumer use product categories reported in the 2016 CDR (U.S. EPA, 2016b). Then, EPA identified the subcategories by supplementing CDR data with information from *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Tetrachloroethylene (Perchloroethylene)* and *Use and Market Profile for Tetrachloroethylene*, both available in the public docket (EPA-HQ-OPPT-2016-0732). For risk evaluations, EPA will assess each use subcategory by identifying all potential sources of release and human exposure associated with that subcategory.

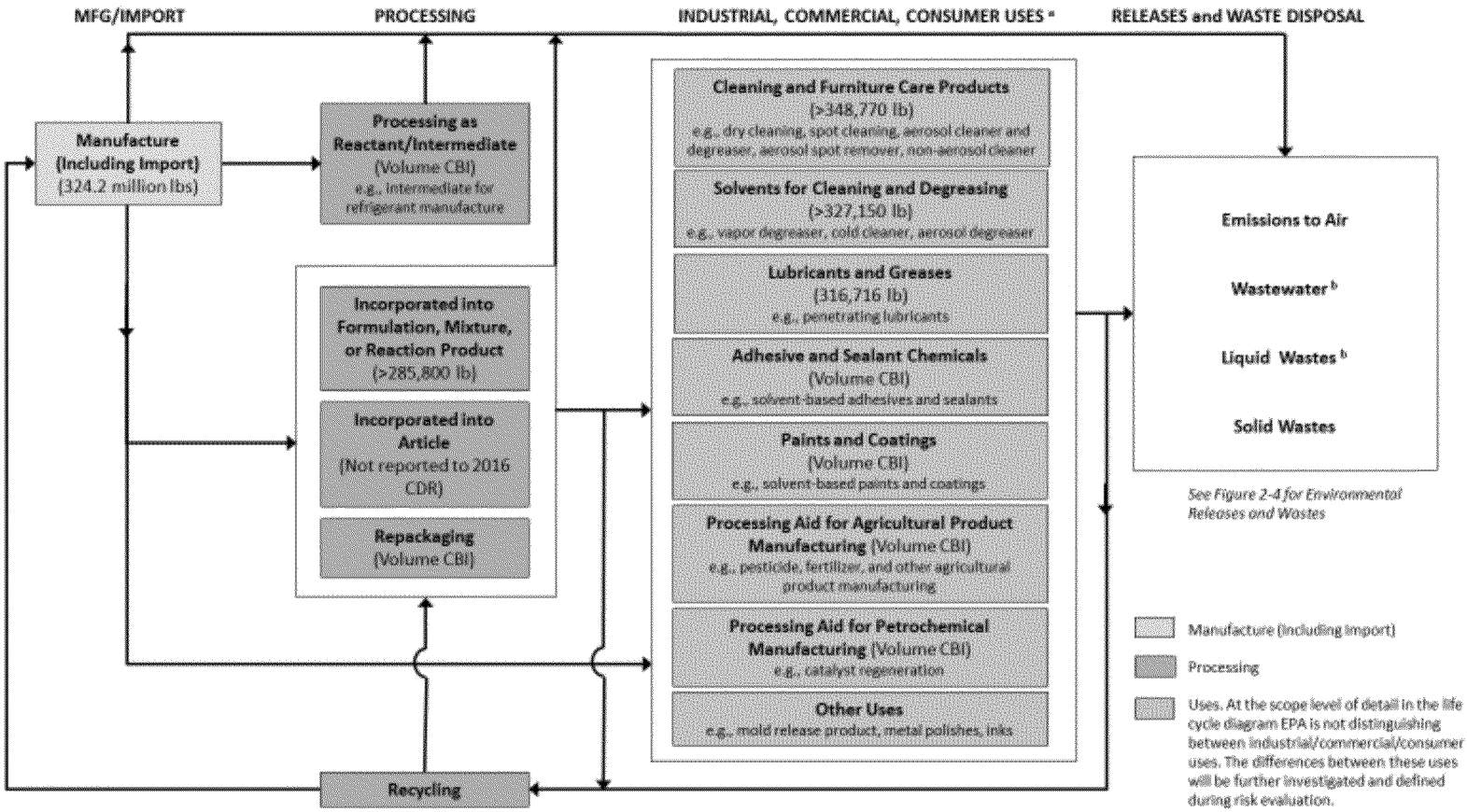


**Figure 2-1. Initial Perchloroethylene Life Cycle Diagram**

The initial life cycle diagram depicts the conditions of use that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, use (industrial, commercial, consumer, where distinguishable), distribution and disposal. The production volumes shown are for reporting year 2015 from the 2016 CDR reporting period (U.S. EPA, 2016b). Activities related to distribution (e.g., loading, unloading) will be considered throughout the perchloroethylene life cycle, rather than using a single distribution scenario.

[a] See Table 2-3 for additional uses not mentioned specifically in this diagram.

[b] Wastewater: combination of water and organic liquid, where the organic content is less than 50 %. Liquid Wastes: combination of water and organic liquid, where the organic content is greater than 50 %.

Descriptions of the industrial, commercial and consumer use categories identified from the 2016 CDR (U.S. EPA, 2016b) and included in the life cycle diagram are summarized below. The descriptions provide a brief overview of the use category; Appendix B contains more detailed descriptions (e.g., process descriptions, worker activities, process flow diagrams, equipment illustrations) for each manufacture, processing, use and disposal category. The descriptions provided below are primarily based on the corresponding industrial function category and/or commercial and consumer product category descriptions from the 2016 CDR and can be found in EPA's *Instructions for Reporting 2016 TSCA Chemical Data Reporting* (U.S. EPA, 2016a).

The "**Cleaning and Furniture Care Products**" category encompasses chemical substances contained in products that are used to remove dirt, grease, stains and foreign matter from furniture and furnishings or to cleanse, sanitize, bleach, scour, polish, protect or improve the appearance of surfaces (U.S. EPA, 2016a). This category includes a wide variety of uses, including, but not limited to, the use of perchloroethylene as a commercial dry cleaning solvent, in spot cleaning formulations, in automotive care products such as brake cleaners and engine degreasers, and other aerosol and non-aerosol type cleaners.

The "**Solvents for Cleaning and Degreasing**" category encompasses chemical substances used to dissolve oils, greases and similar materials from a variety of substrates including metal surfaces, glassware and textile (U.S. EPA, 2016a). This category includes the use of perchloroethylene in vapor degreasing, cold cleaning, in industrial and commercial aerosol degreasing products and in industrial dry cleaning applications, including spot cleaning.

The "**Lubricants and Greases**" category encompasses chemical substances contained in products used to reduce friction, heat generation and wear between solid surfaces (U.S. EPA, 2016a). This category covers a variety of lubricants and greases that contain perchloroethylene including, but not limited to, penetrating lubricants, cutting tool coolants, aerosol lubricants, red greases, white lithium greases, silicone-based lubricants and chain and cable lubricants.

The "**Adhesives and Sealants**" category encompasses chemical substances contained in adhesive and sealant products used to fasten or bond other materials together (U.S. EPA, 2016a). EPA anticipates that the primary subcategory will be the use of perchloroethylene in solvent-based adhesives and sealants. This category covers industrial, commercial and consumer uses of adhesives and sealants.

The "**Paints and Coatings**" category encompasses chemical substances contained in paints, lacquers, varnishes and other coating products that are applied as a thin continuous layer to a surface (U.S. EPA, 2016a; OECD, 2009c). Coating may provide protection to surfaces from a variety of effects such as corrosion and UV degradation; may be purely decorative; or provide other functions (OECD, 2009c). EPA anticipates that the primary subcategory will be the use of perchloroethylene in solvent-based coatings. This category covers industrial, commercial and consumer uses of paints and coatings.

The "**Processing aids for agricultural product manufacturing**" category encompasses a variety of chemical substances that are used to improve the processing characteristics or operation of process equipment or to alter or buffer the pH of the substance (U.S. EPA, 2016a). Processing aids do not become a part of the final reaction product and are not intended to affect the function of the product (U.S. EPA, 2016a). Based on the 2016 CDR, EPA anticipates the primary subcategory will be the use in

pesticide, fertilizer or other agricultural product manufacturing; however, the exact use in this subcategory has yet to be identified be EPA. Examples of processing aids include buffers, dehumidifiers, dehydrating agents, sequestering agents and chelators (U.S. EPA, 2016a).

The "**Processing aid for petrochemical manufacturing**" category is similar to the "Processing aid for agricultural product manufacturing" category except the chemicals are use specifically during the production of oil, gas and other similar products (U.S. EPA, 2016a). Based on the U.S. EPA (2016a) and a Dow Chemical Company Product Safety Assessment (Dow Chemical Co, 2008), EPA anticipates the primary subcategory will be the use of perchloroethylene for catalyst regeneration in petrochemical manufacturing.

Table 2-3 summarizes each life cycle stage and the corresponding categories and subcategories of conditions of use for perchloroethylene that EPA expects to consider in the risk evaluation. Using the 2016 CDR, EPA identified industrial processing or use activities, industrial function categories and commercial and consumer use product categories. EPA identified the subcategories by supplementing CDR data with other published literature and information obtained through stakeholder consultations. For risk evaluations, EPA intends to consider each life cycle stage (and corresponding use categories and subcategories) and assess relevant potential sources of release and human exposure associated with that life cycle stage.

**Table 2-3. Categories and Subcategories of Use for Perchloroethylene**

| Life Cycle Stage | Category [a] | Subcategory [b] | References |
|---|---|---|---|
| Manufacture | Domestic manufacture | Domestic manufacture | U.S. EPA (2016b) |
| | Import | Import | U.S. EPA (2016b) |
| Processing | Processing as a reactant or intermediate | Intermediate in industrial gas manufacturing | U.S. EPA (2016b); Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0013; Public Comment, Public Comment, EPA-HQ-OPPT-2016-0732-DRAFT-0018; Public Comment, Public Comment, EPA-HQ-OPPT-2016-0732-0033 |
| | | Intermediate in basic organic chemical manufacturing | U.S. EPA (2016b); Market Profile, EPA-HQ-OPPT-2016-0732; |
| | | Intermediate in petroleum refineries | U.S. EPA (2016b); Market Profile, EPA-HQ-OPPT-2016-0732; Public |

| Life Cycle Stage | Category [a] | Subcategory [b] | References |
|---|---|---|---|
| | | | Comment, EPA-HQ-OPPT-2016-0732-0018 |
| | | Residual or byproduct | Public Comment, EPA-HQ-OPPT-2016-0732-0013 |
| | Incorporated into formulation, mixture or reaction product | Cleaning and degreasing products | U.S. EPA (2016b); Public Comment, EPA-HQ-OPPT-2016-0732-0017 |
| | | Adhesive and sealant products | U.S. EPA (2016b) |
| | | Paint and coating products | U.S. EPA (2016b) |
| | | Other chemical products and preparations | U.S. EPA (2016b) |
| | Incorporated into articles | Plastic and rubber products | Use Document, EPA-HQ-OPPT-2016-0732-0003 |
| | Repackaging | Solvent for cleaning or degreasing | U.S. EPA (2016b) |
| | | Intermediate | U.S. EPA (2016b) |
| | Recycling | Recycling | U.S. EPA (2016b) |
| Distribution in commerce | Distribution | Distribution | Use Document, EPA-HQ-OPPT-2016-0732-0003 |
| Industrial use | Solvents (for cleaning or degreasing) | Solvents and/or Degreasers (cold, aerosol spray or vapor degreaser; not specified in comment) | Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0022; Public Comment, EPA-HQ-OPPT-2016-0732-0029 |
| | | Batch vapor degreaser (e.g., open-top, closed-loop) | U.S. EPA (1985b); Public Comment, EPA-HQ-OPPT-2016-0732-0015; Public Comment, EPA-HQ-OPPT-2016-0732-0027 |
| | | In-line vapor degreaser (e.g., conveyorized, web cleaner) | U.S. EPA (1985b); Public Comment, EPA-HQ-OPPT-2016-0732-0014 |

| Life Cycle Stage | Category [a] | Subcategory [b] | References |
|---|---|---|---|
| | Solvents (for cleaning or degreasing) | Cold cleaner | Market Profile, EPA-HQ-OPPT-2016-0732; U.S. EPA (1985b); Public Comment, EPA-HQ-OPPT-2016-0732-0017 |
| | | Aerosol spray degreaser/cleaner | Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0009; Public Comment, EPA-HQ-OPPT-2016-0732-0017 |
| | | Dry cleaning solvent | Market Profile, EPA-HQ-OPPT-2016-0732; U.S. EPA (2006a) |
| | | Spot cleaner | Market Profile, EPA-HQ-OPPT-2016-0732; U.S. EPA (2006a); Public Comment, EPA-HQ-OPPT-2016-0732-0009 |
| | Lubricants and greases | Lubricants and greases (e.g., penetrating lubricants, cutting tool coolants, aerosol lubricants) | U.S. EPA (2016b); Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0027; Public Comment, EPA-HQ-OPPT-2016-0732-0029 |
| | Adhesive and sealant chemicals | Solvent-based adhesives and sealants | U.S. EPA (2016b); Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0009; Public Comment, EPA-HQ-OPPT-2016-0732-0015; Public Comment, EPA-HQ-OPPT-2016-0732-0022; Public |

| Life Cycle Stage | Category [a] | Subcategory [b] | References |
|---|---|---|---|
| | | | Comment, EPA-HQ-OPPT-2016-0732-0027 |
| | Paints and coatings including paint and coating removers | Solvent-based paints and coatings | U.S. EPA (2016b); Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0006; Public Comment, EPA-HQ-OPPT-2016-0732-0009; Public Comment, EPA-HQ-OPPT-2016-0732-0015; Public Comment, EPA-HQ-OPPT-2016-0732-0020; Public Comment, EPA-HQ-OPPT-2016-0732-0027 |
| | Processing aids, not otherwise listed | Pesticide, fertilizer and other agricultural chemical manufacturing | U.S. EPA (2016b) |
| | Processing aids, specific to petroleum production | Catalyst regeneration in petrochemical manufacturing | U.S. EPA (2016b); Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Dow Chemical Co (2008); Public Comment, EPA-HQ-OPPT-2016-0732-0018; Public Comment, EPA-HQ-OPPT-2016-0732-0027 |
| | Other uses | Textile processing | Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732 |
| | | Wood furniture manufacturing | Use Document, EPA-HQ-OPPT-2016-0732-0003 |

| Life Cycle Stage | Category [a] | Subcategory [b] | References |
|---|---|---|---|
| | | Laboratory chemicals | Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0015 |
| | | Foundry applications | Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732 |
| Commercial/consumer use | Cleaning and furniture care products | Cleaners and degreasers (other) | Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0009; Public Comment, EPA-HQ-OPPT-2016-0732-0017; Public Comment, EPA-HQ-OPPT-2016-0732-0022; EPA-HQ-OPPT-2016-0732-0023; Public Comment, EPA-HQ-OPPT-2016-0732-0027; Public Comment, EPA-HQ-OPPT-2016-0732-0029 |
| | | Dry cleaning solvent | Market Profile, EPA-HQ-OPPT-2016-0732; U.S. EPA (2006a); Public Comment, EPA-HQ-OPPT-2016-0732-0007; Public Comment, EPA-HQ-OPPT-2016-0732-0009 |
| | | Spot cleaner | Market Profile, EPA-HQ-OPPT-2016-0732; U.S. EPA (2006a); Public Comment, EPA-HQ-OPPT-2016-0732-0009 |

| Life Cycle Stage | Category [a] | Subcategory [b] | References |
|---|---|---|---|
| | | Automotive care products (e.g., engine degreaser and brake cleaner) | U.S. EPA (2016b), Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0017; Public Comment, EPA-HQ-OPPT-2016-0732-0027 |
| | | Aerosol cleaner | Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0009 |
| | | Non-aerosol cleaner | Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0009 |
| | Lubricants and greases | Lubricants and greases (e.g., penetrating lubricants, cutting tool coolants, aerosol lubricants) | U.S. EPA (2016b); Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0027; Public Comment, EPA-HQ-OPPT-2016-0732-0029 |
| | Adhesives and sealant chemicals | Adhesives for arts and crafts | U.S. EPA (2016b); Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0009 |
| | | Light repair adhesives | U.S. EPA (2016b); Use Document, EPA-HQ-OPPT-2016-0732-0003 |

| Life Cycle Stage | Category [a] | Subcategory [b] | References |
|---|---|---|---|
| | Paints and coatings | Solvent-based paints and coatings | U.S. EPA (2016b); Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0009; Public Comment, EPA-HQ-OPPT-2016-0732-0020; Public Comment, EPA-HQ-OPPT-2016-0732-0027 |
| | Other uses | Carpet cleaning | Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0009 |
| | | Laboratory chemicals | Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732 |
| | | Metal (e.g., stainless steel) and stone polishes | Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732 |
| | | Inks and ink removal products | Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732 |
| | | Welding | Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; |
| | | Photographic film | Use Document, EPA-HQ-OPPT-2016-0732-0003 |

| Life Cycle Stage | Category [a] | Subcategory [b] | References |
|---|---|---|---|
| | | Mold cleaning, release and protectant products | Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0017 |
| Disposal | Emissions to air | Air | Use Document, EPA-HQ-OPPT-2016-0732-0003 |
| | Wastewater | Industrial pre-treatment | |
| | | Industrial wastewater treatment | |
| | | Publicly owned treatment works (POTW) | |
| | | Underground injection | |
| | Solid wastes and liquid wastes | Municipal landfill | |
| | | Hazardous landfill | |
| | | Other land disposal | |
| | | Municipal waste incinerator | |
| | | Hazardous waste incinerator | |
| | | Off-site waste transfer | |

[a] These categories appear in the Life Cycle Diagram, reflect CDR codes and broadly represent conditions of use of perchloroethylene in industrial and/or commercial settings.
[b] These subcategories reflect more specific uses of perchloroethylene.

The uses of perchloroethylene include the production of fluorinated compounds, dry cleaning and vapor degreasing, as well as a number of smaller uses. Nearly 65% of the production volume of perchloroethylene is used to produce fluorinated compounds, such as hydrofluorocarbons (HFCs) and hydrochlorofluorocarbons (HCFCs) (NTP, 2014; ICIS, 2011). HFCs 134a and 125 are alternatives to chlorofluorocarbons (CFCs) and HCFCs, which are ozone depleting substances (ODSs), and the subject of a phase-out (https://www.epa.gov/ods-phaseout). HCFCs are transitional substances in the phase-out of ODSs (ICIS, 2011) (Public Comment, EPA-HQ-OPPT-2016-0732-0033). Previously, perchloroethylene was widely used to manufacture CFCs (esp. trichlorotrifluoroethane (CFC-113)) until CFCs were essentially eliminated in the United States by the Montreal Protocol; a relatively small amount of CFC-113 is still produced for exempted uses (teleconference with Honeywell, 2017; summary is available in the docket: EPA-HQ-OPPT-2016-0732).

The second largest use of perchloroethylene (~15%) is as a solvent in dry cleaning facilities (NTP, 2014). Perchloroethylene is non-flammable and effectively dissolves fats, greases, waxes and oils, without harming natural or human-made fibers. These properties enabled it to replace traditional petroleum solvents (ATSDR, 2014; Dow Chemical Co, 2008; Tirsell, 2000). The demand for perchloroethylene dry

cleaning solvents has steadily declined as a result of the improved efficiency of dry cleaning equipment, increased chemical recycling and the popularity of wash-and-wear fabrics that eliminate the need for dry cleaning (ATSDR, 2014). Perchloroethylene is also used in dry cleaning detergent and dry cleaning sizing.

Approximately 60% of dry cleaning machines now use perchloroethylene as a solvent (DLI and NCA, 2017). In 1991, EPA estimated that 83% of all dry cleaning facilities used perchloroethylene as solvent (U.S. EPA, 1991). In 2008, the Halogenated Solvents Industry Association (HSIA) estimated that 70% of dry cleaners used perchloroethylene as dry cleaning solvent (EPA-HQ-OPPT-2016-0732-0027). Similarly, in 2011, King County, WA conducted a profile of the dry cleaning industry and found that 69% of respondents (105 of the 152 respondents) used perchloroethylene in their primary machine (Whittaker and Johanson, 2011). Hence, there appears to be a trend towards alternatives to perchloroethylene in dry cleaning. According to the dry cleaning industry, a majority of new perchloroethylene dry cleaning machines are sold in locations where local fire codes preclude the use of Class III combustible alternative solvents or where the nature of the dry cleaning operation requires the use of perchloroethylene (DLI and NCA, 2017).

The third most prevalent use of perchloroethylene (~10%) is as a vapor degreasing solvent (NTP, 2014). Perchloroethylene can be used to dissolve many organic compounds, select inorganic compounds and high-melting pitches and waxes making it ideal for cleaning contaminated metal parts and other fabricated materials (ATSDR, 2014). It is a very good solvent for greases, fats, waxes, oils, bitumen, tar and many natural and synthetic resins for use in chemical cleaning systems, degreasing light and heavy metals, degreasing pelts and leather (tanning), extraction of animal and vegetable fats and oils and textile dyeing (solvent for dye baths) (Stoye, 2000). Perchloroethylene is also used in cold cleaning, which is similar to vapor degreasing, except that cold cleaning does not require the solvent to be heated to its boiling point in order to clean a given component. Vapor degreasing and cold cleaning scenarios may include a range of open-top or closed systems, conveyorized/enclosed/inline systems, spray wands, dip containers and wipes.

Perchloroethylene has many other uses, which collectively constitute ~10% of the production volume. EPA's search of safety data sheets, government databases and other sources found over 375 products containing perchloroethylene. These uses include (but are not limited to):

- Adhesives
- Aerosol degreasing
- Brake cleaner
- Laboratories
- Lubricants
- Mold cleaners, releases and protectants
- Oil refining
- Sealants
- Stainless steel polish
- Tire buffers and cleaners
- Vandal mark removers

Many of these uses include consumer products, such as adhesives (arts and crafts, as well as light repairs), aerosol degreasing, brake cleaners, aerosol lubricants, sealants, sealants for gun ammunition,

stone polish, stainless steel polish and wipe cleaners. The uses of perchloroethylene in consumer adhesives and brake cleaners are especially prevalent; EPA has found 16 consumer adhesive products and 14 consumer brake cleaners containing perchloroethylene [see *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Tetrachloroethylene (Perchloroethylene)* and *Use and Market Profile for Tetrachloroethylene*, EPA-HQ-OPPT-2016-0732-0003].

## 2.3 Exposures

For TSCA exposure assessments, EPA expects to evaluate exposures and releases to the environment resulting from the conditions of use applicable to perchloroethylene. Post-release pathways and routes will be described to characterize the relationship or connection between the conditions of use of perchloroethylene and the exposure to human receptors, including potentially exposed or susceptible subpopulations and ecological receptors. EPA will take into account, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to perchloroethylene.

### 2.3.1 Fate and Transport

Environmental fate includes both transport and transformation processes. Environmental transport is the movement of the chemical within and between environmental media. Transformation occurs through the degradation or reaction of the chemical with other species in the environment. Hence, knowledge of the environmental fate of the chemical informs the determination of the specific exposure pathways and potential human and environmental receptors EPA expects to consider in the risk evaluation. Table 2-4 provides environmental fate data that EPA has identified and considered in developing the scope for perchloroethylene.

**Table 2-4. Environmental Fate Characteristics of Perchloroethylene**

| Property or Endpoint | Value [a] | References |
|---|---|---|
| Direct photodegradation | 3 years (atmosphere) | ECB (2005) |
| Indirect photodegradation | 96 days (atmosphere) | ECB (2005) |
| Hydrolysis half-life | Months-years | ECB (2005) |
| Biodegradation | No degradation (aerobic in mixed and pure culture, modified shake flask, river die-away study, sewage inoculated).<br><br><1 day to weeks (anaerobic, based on multiple studies). | ECB (2005) |
| Bioconcentration factor (BCF) | 40 and 49 (fish)<br>312 and 101 (marine algae) | ECB (2005) |
| Bioaccumulation factor (BAF) | 46 (estimated) | ECB (2005); (U.S. EPA, 2012a) |
| Organic carbon:water partition coefficient (log $K_{oc}$) | 1.6-2.7<br>2.9 (estimated) | ECB (2005) |

[a] Measured unless otherwise noted.

The environmental fate and transport of perchloroethylene has been reviewed by ATSDR (2014), WHO (2006) and ECB (2005). This section was prepared based on these reviews.

Based on its vapor pressure and Henry's Law constant perchloroethylene will tend to partition from water to air and, to a lesser extent soil to air. The persistence of perchloroethylene is complicated, with results highly dependent on specific environmental and microbial conditions (WHO, 2006; ECB, 2005). In the vapor phase perchloroethylene can be slowly transformed by reaction with hydroxyl and other radicles with half-lives of months or greater, and long-range transport may occur. In water, perchloroethylene is generally stable. Aqueous photolysis has not been observed and is not expected to be a significant degradation processes. Hydrolysis, if it occurs, is expected to be slow with a half-life ($t_{1/2}$) of greater than months to years.

Aerobic biodegradation may occur but degradation is slow with rates and pathways that are environment- and population-dependent. Anaerobic degradation has been observed to be faster than aerobic degradation under some conditions with acclimated microbial populations.

Perchloroethylene in surface waters can be expected to volatilize into the atmosphere. However, perchloroethylene is denser than water and only slightly soluble in water. In soil and aquifers, it will tend to remain in the aqueous phase and be transported to ground water. Anaerobic biodegradation is expected to be a significant degradation mechanism in soil and ground water.

In ground water, perchloroethylene may be present as a dense non-aqueous phase liquid (DNAPL), which, because it is denser than water, means that it will form a separate phase, often at the base of an aquifer. The half-life degradation rate in ground water is estimated to be between one to two years, based on aqueous aerobic biodegradation (Howard, 1991) but may be considerably longer under certain conditions.

In soil and sediment, aerobic and anaerobic degradation can occur but is generally slow. Several microbial species have been identified that are capable of degrading perchloroethylene under certain conditions but biodegradation in the environment is expected to be slow with $t_{1/2}$ of months or greater.

With BCFs and BAFs ranging from 40 to 100, ATSDR (2014), WHO (2006) and ECB (2005) indicate that there is limited potential for perchloroethylene to bioaccumulate in plants and animals.

### 2.3.2 Releases to the Environment

Releases to the environment from conditions of use (e.g., industrial and commercial processes, commercial or consumer uses resulting in down-the-drain releases) are one component of potential exposure and may be derived from reported data that are obtained through direct measurement, calculations based on empirical data and/or assumptions and models.

A key source of information that EPA expects to consider in evaluating exposure are data reported under the TRI program. Under the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313 rule, perchloroethylene is a TRI-reportable substance effective January 1, 1987.

Table 2-5 provides production-related waste managed data (also referred to as waste managed) for perchloroethylene reported by industrial facilities to the TRI program for 2015. Table 2-6 provides more detailed information on the quantities released to air or water or disposed of on land.

**Table 2-5. Summary of Perchloroethylene TRI Production-Related Waste Managed in 2015 (lbs)**

| Number of Facilities | Recycling | Energy Recovery | Treatment | Releases [a, b, c] | Total Production Related Waste |
|---|---|---|---|---|---|
| 27 | 46,406,761 | 2,341,981 | 15,130,958 | 1,167,367 | 65,047,068 |

Data source: 2015 TRI Data (updated March 2017) U.S. EPA (2017).
[a] Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.
[b] Does not include releases due to one-time event not associated with production such as remedial actions or earthquakes.
[c] Counts all releases including release quantities transferred and release quantities disposed of by a receiving facility reporting to TRI.

In 2015, 27 facilities reported a total of 65 million pounds of perchloroethylene waste managed. Of this total, 46 million pounds were recycled, 2.3 million pounds were recovered for energy, 15 million pounds were treated and 1.1 million pounds were released into the environment. Of these releases, the majority, or 63 percent, were released to air: 0.7 million pounds were released to air (stack and fugitive air emissions), 349 pounds were released to water (surface water discharges), 78 thousand pounds were released to land (of which disposal to Resource Conservation and Recovery Act (RCRA) Subtitle C landfills is the primary disposal method) and 334 thousand pounds were released in other forms such as to waste brokers.

Release quantities in Table 2-6 are more representative of actual releases during the year. Production-related waste managed shown in Table 2-5 excludes any quantities reported as catastrophic or one-time releases (TRI section 8 data), while release quantities shown in Table 2-6 include both production-related and non-routine quantities (TRI section 5 and 6 data). Table 2-5 counts all release quantities reported to TRI while Table 2-6 counts releases once at final disposition, accounting for transfers of chemical waste from one TRI reporting facility and received by another TRI reporting facility for final disposal. As a result, release quantities may differ slightly and may further reflect differences in TRI calculation methods for reported release range estimates (U.S. EPA, 2017).

**Table 2-6. Summary of Perchloroethylene TRI Releases to the Environment in 2015 (lbs)**

| | | Air Releases | | | Land Releases | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Number of Facilities | Stack Air Releases | Fugitive Air Releases | Water Releases | Class I Under-ground Injection | RCRA Subtitle C Landfills | All other Land Disposal [a] | Other Releases [a] | Total Releases [b, c] |
| Subtotal | | 435,558 | 279,073 | | 272 | 78,036 | 414 | | |
| Totals | 27 | 714,631 | | 349 | 78,722 | | | 334,148 | 1,127,864 |

Data source: 2015 TRI Data (updated March 2017) U.S. EPA (2017).
[a] Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.
[b] These release quantities do include releases due to one-time events not associated with production such as remedial actions or earthquakes.
[c] Counts release quantities once at final disposition, accounting for transfers to other TRI reporting facilities that ultimately dispose of the chemical waste.

While production-related waste managed shown in Table 2-5 excludes any quantities reported as catastrophic or one-time releases (TRI Section 8 data), release quantities shown in Table 2-6 include both production-related and non-routine quantities (TRI section 5 and 6 data). As a result, release quantities may differ slightly and may further reflect differences in TRI calculation methods for reported release range estimates (U.S. EPA, 2017).

Other sources of information provide evidence of releases of perchloroethylene, including EPA effluent guidelines (EGs) promulgated under the Clean Water Act (CWA), National Emission Standards for Hazardous Air Pollutants (NESHAPs) promulgated under the Clean Air Act (CAA) or other EPA standards and regulations that set legal limits on the amount of perchloroethylene that can be emitted to a particular media. EPA expects to consider these data in conducting the exposure assessment component of the risk evaluation for perchloroethylene.

### 2.3.3 Presence in the Environment and Biota

Monitoring studies or a collection of relevant and reliable monitoring studies provide(s) information that can be used in an exposure assessment. Monitoring studies that measure environmental concentrations or concentrations of chemical substances in biota provide evidence of exposure. Monitoring and biomonitoring data were identified in EPA's data search for perchloroethylene:

***Environment***

Perchloroethylene has been found in air, soil, surface water, salt water, drinking water, aquatic organisms and terrestrial organisms(WHO, 2006). Historic industrial, commercial and military use of perchloroethylene, including unregulated or improper disposal of perchloroethylene wastes, has resulted in location-specific soil and ground water contamination. Perchloroethylene is a common ground water contaminant at hazardous waste sites in the U.S. (ATSDR, 2014) and a common drinking water contaminant (U.S. EPA, 2012b). EPA will evaluate manufacturing, processing, distribution, use, disposal and recycling to identify and characterize current sources of release and contamination.

Urban and industrial areas are prone to higher perchloroethylene air concentrations than rural areas due to the concentration of sources (ATSDR, 2014; U.S. EPA, 2012b; WHO, 2006). EPA air monitoring data from 2013 reported detection of perchloroethylene in 77% of ambient air samples, with 58% of detects above the method detection limit (U.S. EPA, 2015, Table 4.1). Indoor air concentrations of perchloroethylene tend to be greater than concentrations in outdoor air (ATSDR, 2014; U.S. EPA, 2012b).

Perchloroethylene is a common contaminant in municipal drinking water supplies and ground water, with some of the highest measured concentrations in ground water occurring near perchloroethylene contaminated sites (for some examples, see (ATSDR, 2014; WHO, 2006 and references therein). EPA and the USGS National Water Quality Assessment Program (Cycle 1, 1992-2001) reported perchloroethylene contamination in U.S. surface water and ground water in 19.6% of samples (n=5,911) and at 13.2% of sites (n=4,295), with detection in surface water occurring more frequently than in ground water (U.S. EPA, 2009). EPA's Second Six-Year Review Contaminant Occurrence Data reported occurrence of monitored chemicals in U.S. drinking water supplies from 1998 to 2005. The Second Six-Year Review data showed perchloroethylene occurrence in 2.5% of roughly 50,000 public water systems, with thirty-six states reporting drinking water systems with at least one detection above the maximum contaminant level (MCL: 5 µg/L, U.S. EPA, 2009).

***Biota***

The EU Risk Assessment Report (ECB, 2005) summarized data on measured levels of perchloroethylene in biota, including algae, invertebrates, fish and terrestrial plants. Nearly all reported concentrations are from locations in the EU and are below ~25 µg/kg.

Perchloroethylene has been measured in biomonitoring samples of U.S. populations. A subset of National Health and Nutrition Examination Survey (NHANES) data (1999-2000) reported in Lin et al. (2008) show the presence of perchloroethylene in 77% of human blood samples from non-smoking U.S. adults. Updated biomonitoring data reported by the Centers for Disease Control (CDC), sampled between 2001 and 2008, show a possible decline in the prevalence of perchloroethylene in U.S. population human blood samples, however limits of detection differ between the two data sets, complicating direct comparison. The CDC data show a decreasing concentration trend over the timeframe of data collection (CDC, 2017).

### 2.3.4 Environmental Exposures

The manufacturing, processing, use and disposal of perchloroethylene can result in releases to the environment. EPA expects to consider exposures to the environment and ecological receptors that occur via the exposure pathways or media shown in Figure 2-4 in conducting the risk evaluation for perchloroethylene.

### 2.3.5 Human Exposures

The manufacturing, processing, distribution, use and disposal of perchloroethylene can result in releases to the environment. EPA expects to consider exposures to the environment and ecological receptors that occur via the exposure pathways or media shown in Figure 2-4 in conducting the risk evaluation for perchloroethylene.

#### 2.3.5.1 Occupational Exposures

EPA expects to consider worker activities where there is a potential for exposure under the various conditions of use described in Section 2.2. In addition, EPA expects to consider exposure to occupational non-users, who do not directly handle the chemical but perform work in an area where the chemical is present. When data and information are available to support the analysis, EPA also expects to consider the effect(s) that engineering controls and/or personal protective equipment have on occupational exposure levels.

Workers and occupational non-users may be exposed to perchloroethylene when performing activities associated with the conditions of use described in Section 2.2, that may include:

- Unloading and transferring perchloroethylene to and from storage containers to process vessels;
- Using perchloroethylene in process equipment (e.g., vapor degreasing machine);
- Applying formulations and products containing perchloroethylene onto substrates (e.g., spray applying coatings or adhesives containing perchloroethylene);
- Performing other work activities in or near areas where perchloroethylene is used.

Based on these activities, EPA expects to consider inhalation exposure to vapor and mists, and dermal exposure, including skin contact with liquids and vapors for workers and occupational non-users. EPA also expects to consider potential worker exposure through mists that deposit in the upper respiratory tract and are swallowed.

The United States has several regulatory and non-regulatory exposure limits for perchloroethylene: An OSHA Permissible Exposure Limit (PEL) of 100 ppm 8-hour time-weighted average (TWA) (OSHA, 1997) and an American Conference of Government Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) of 25 ppm 8-hour TWA (ACGIH, 2001). The influence of these exposure limits on occupational exposures will be considered in the occupational exposure assessment. Also, the National Institute for Occupational Safety and Health (NIOSH) indicates that perchloroethylene has an immediately dangerous to life and health (IDLH) value of 150 ppm based on effects that might occur from a 20-30-minute exposure, and NIOSH provides a notation that perchloroethylene is a potential occupational carcinogen (NIOSH, 1994).

Key data that inform occupational exposure assessment and which EPA expects to consider include: the OSHA Chemical Exposure Health Data (CEHD) and NIOSH Health Hazard Evaluation (HHE) program data. OSHA data are workplace monitoring data from OSHA inspections. The inspections can be random or targeted or can be the result of a worker complaint. OSHA data can be obtained through the OSHA Integrated Management Information System (IMIS) at https://www.osha.gov/oshstats/index.html

Table_Apx B- 1 in Appendix B provides a summary of industry sectors with perchloroethylene personal monitoring air samples obtained from OSHA inspections conducted between 2011 and 2016. NIOSH HHEs are conducted at the request of employees, union officials or employers and help inform potential hazards at the workplace. HHEs can be downloaded at https://www.cdc.gov/niosh/hhe/. During the problem formulation, EPA will review these data and evaluate their utility in the risk evaluation.

#### 2.3.5.2 Consumer Exposures

Perchloroethylene can be found in consumer and/or commercial products that are readily available for public purchase at common retailers (EPA-HQ-OPPT-2016-0732-0003, Sections 3 and 4 and Table 2-3) and can therefore result in exposures to consumers.

Exposures routes for consumers using perchloroethylene-containing products may include inhalation of vapors mists and aerosols (e.g., aerosols from spray applications), dermal exposure to products and oral exposure to mists that deposit in the upper respiratory tract and are swallowed. Although unlikely given the physical-chemical properties, EPA also expects to consider oral ingestion via oral route such as from incidental ingestion of methylene chloride residue on hands and body.

EPA expects to consider inhalation, dermal and oral exposures to consumers and bystanders associated with the consumer use in the home.

#### 2.3.5.3 General Population Exposures

Wastewater/liquid wastes, solid wastes or air emissions of perchloroethylene could result in potential pathways for oral, dermal or inhalation exposure to the general population. EPA will consider each media, route and pathway to estimate general population exposures.

***Inhalation***

General population inhalation exposure to perchloroethylene in air may result from industrial manufacturing and processing plant fugitive emissions. Perchloroethylene volatizes from contaminated soil and shallow ground water, possibly resulting in elevated outdoor inhalation exposure. Through a

process known as vapor intrusion, volatized perchloroethylene may also infiltrate residential and commercial buildings through cracks in floors, crawl spaces, pipe fittings and toilet and sewer junctions, leading to elevated indoor concentrations of perchloroethylene and greater inhalation exposure (ATSDR, 2014; U.S. EPA, 2012c). In addition, inhalation exposures to perchloroethylene may occur due to volatilization of perchloroethylene from contaminated water (municipal or well water) during showering and bathing (U.S. EPA, 2012b).

Families of workers with occupational perchloroethylene exposure are exposed secondarily by perchloroethylene volatilization from workers clothing, and from exhaled breath, as un-metabolized perchloroethylene is exhaled on the breath as the primary excretion mechanism in humans (ATSDR, 2014; U.S. EPA, 2012b).

Indoor emissions, from the use of perchloroethylene containing products and articles (e.g., degreasers; recently dry-cleaned clothing), may also be sources of perchloroethylene in indoor air (ATSDR, 2014; U.S. EPA, 2012b).

Based on these potential sources and pathways of exposure, EPA expects to consider inhalation exposures of the general population to air containing perchloroethylene that may result from the conditions of use of perchloroethylene.

***Oral***

The general population may ingest perchloroethylene via contaminated drinking water, ground water and/or surface water (ATSDR, 2014; U.S. EPA, 2012b). Perchloroethylene enters water supplies through industrial and commercial wastewater and liquid waste streams, sewage sludge land application, wet deposition (rain) and leaching from contaminated soils (U.S. EPA, 2009). Oral ingestion pathways may include exposure to contaminated drinking water or breast milk. EPA also expects to consider ingestion via the oral route such as from incidental ingestion of perchloroethylene residue on the hand/body.The EU Risk Assessment Report (ECB, 2005) indicates that perchloroethylene may be present in fish, although EPA does not anticipate fish ingestion to be a significant general population exposure pathway, as perchloroethylene has a low bioaccumulation potential in aquatic organisms (BCF 40 50`, Kow < 3) (WHO, 2006).

Based on these potential sources and pathways of exposure, EPA expects to consider oral exposures to the general population that may result from the conditions of use of perchloroethylene.

***Dermal***

Exposure to perchloroethylene may occur via use of products containing perchloroethylene, and through dermal contact with dry-cleaned fabrics or other articles treated with products containing perchloroethylene (U.S. EPA, 2012b). Dermal exposure to perchloroethylene from showering, bathing and swimming is also possible (U.S. EPA, 2012b).

Based on these potential sources and pathways of exposure, EPA expects to consider dermal exposures to the general population that may result from the conditions of use of perchloroethylene.

#### 2.3.5.4 Potentially Exposed or Susceptible Subpopulations

TSCA requires that the determination of whether a chemical substance presents an unreasonable risk include consideration of unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation" by EPA. TSCA § 3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly."

In this section, EPA addresses the potentially exposed or susceptible subpopulations identified as relevant based on greater exposure. EPA will address the subpopulations identified as relevant based on greater susceptibility in the hazard section.

Of the human receptors identified in the previous sections, EPA identifies the following as potentially exposed or susceptible subpopulations due to their *greater exposure*, that EPA expects to consider in the risk evaluation:

- Workers and occupational non-users, including women of childbearing age.
- Consumers and bystanders associated with consumer use. Perchloroethylene has been identified as being used in products available to consumers; however, only some individuals within the general population may use these products. Therefore, those who do use these products, including hobbyists, are a potentially exposed or susceptible subpopulation due to greater exposure.
- Other groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use identified in Section 2.2 that result in releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, distribution, use or disposal sites).

In developing exposure scenarios, EPA will evaluate available data to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or lifestage (e.g., children's crawling, mouthing or hand-to-mouth behaviors) and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities, duration or location of exposure) when compared with the general population (U.S. EPA, 2006b).

For example, the behavior of children may put them in closer contact with some sources of perchloroethylene, such as carpet cleaners. The hand-to-mouth/mouthing behaviors of small children may increase accidental ingestion of perchloroethylene from dry cleaned articles and contaminated soils. Children may be exposed via inhalation as bystanders, during consumer use in the home. Although the amount of perchloroethylene children may ingest through water and food is not well described (U.S. EPA, 2012b), children tend to consume more water and food per body weight relative to adults, and have greater skin surface area than adults, relative to weight, which can result in proportionally higher ingestion and dermal exposures.

Perchloroethylene is lipophilic, and accumulates in fatty fluids and tissues in the human body. Subpopulations that may have higher body fat composition, and may be more highly exposed include pubescent and adult women, including women of child-bearing age. The EPA IRIS Assessment for

perchloroethylene (U.S. EPA, 2012b) also identified the developing fetus as potentially exposed, as well as infants consuming breastmilk, particularly for mothers with occupational exposure to perchloroethylene or exposure due to proximity to industrial or commercial sources (U.S. EPA, 2012b). Infants fed by formula may also experience increased perchloroethylene exposure if perchloroethylene is present in drinking water supplies (U.S. EPA, 2012b).

In summary, in the risk evaluation for perchloroethylene, EPA expects to consider the following potentially exposed groups of human receptors: workers, occupational non-user, consumers and bystanders associated with consumer use. As described above, EPA may also identify additional potentially exposed or susceptible subpopulations that will be considered based on greater exposure.

## 2.4 Hazards (Effects)

For scoping, EPA conducted comprehensive searches for data on hazards of perchloroethylene, as described in the supplemental document: *Strategy for Conducting Literature Searches for Perchloroethylene: Supplemental File for the TSCA Scope Document*. Based on initial screening, EPA expects to consider the hazards of perchloroethylene identified in this scope document. However, when conducting the risk evaluation, the relevance of each hazard within the context of a specific exposure scenario will be judged for appropriateness. For example, hazards that occur only as a result of chronic exposures may not be applicable for acute exposure scenarios. This means that it is unlikely that every hazard identified in the scope will be considered for every exposure scenario.

### 2.4.1 Environmental Hazards

For scoping purposes, EPA consulted the following sources of environmental hazard data for perchloroethylene: ECB (2005) and WHO (2006). However, EPA also expects to consider other studies (e.g., more recently published, alternative test data) that have been published since these reviews, as identified in the literature search conducted by the Agency for perchloroethylene (*Perchloroethylene (CASRN 127-18-4) Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0732).

EPA expects to consider the hazards of perchloroethylene to aquatic organisms including fish, aquatic invertebrates and algae potentially exposed under acute and chronic exposure conditions. The ECB (2005) Risk Assessment for perchloroethylene suggests acute and chronic hazard for the environment based on mortality, immobility, cell growth inhibition and reproduction. EPA also expects to consider the hazards of perchloroethylene to terrestrial organisms including soil invertebrates, birds, insects and mammals and amphibians exposed to relevant media under acute and/or chronic exposure conditions.

### 2.4.2 Human Health Hazards

Perchloroethylene has an existing EPA IRIS Assessment (U.S. EPA, 2012b) and a draft ATSDR Toxicological Profile (ATSDR, 2014); hence, many of the hazards of perchloroethylene have been previously compiled and systematically reviewed. EPA has relied heavily on these comprehensive reviews in preparing this scope. EPA also expects to consider other studies (e.g., more recently published, alternative test data) that have been published since these reviews, as identified in the literature search conducted by the Agency for perchloroethylene (*Perchloroethylene (CASRN 127-18-4) Bibliography: Supplemental File for the TSCA Scope Document*). EPA expects to consider all potential hazards associated with perchloroethylene. Based on reasonably available information, the following are the hazards that have been identified in previous government documents and that EPA currently expects will likely be the focus of its analysis.

#### 2.4.2.1 Non-Cancer Hazards

The EPA IRIS Assessment on perchloroethylene (U.S. EPA, 2012b) evaluated the following non-cancer hazards that may be associated with perchloroethylene exposures: the central nervous system (neurotoxicity), kidney, liver and development and reproduction. In general, neurological effects were found to be associated with lower perchloroethylene inhalation exposures. According to the EPA IRIS Assessment (U.S. EPA, 2012b), support for an association with immune and blood effects were less well characterized. In their draft Toxicological Profile for perchloroethylene, ATSDR (2014) identified similar hazard concerns. The National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL, 2009) also identified irritation as a hazard concern.

***Acute Toxicity***

Data from acute studies in animals and human incidents indicate that short term exposure to perchloroethylene may cause irritation and neurotoxicity and can impair cognitive function in humans(U.S. EPA, 2012b). An Acute Exposure Guidance Limit (AEGL) values, established by the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL, 2009), has been developed based on irritation to humans (AEGL-1), ataxia in rodents (AEGL-2), and lethality in mice (AEGL-3) (NAC/AEGL, 2009).

***Neurotoxicity***

Evidence in humans and animals show that chronic exposure to perchloroethylene can cause neurotoxicity, resulting in decrements in color vision, visuospatial memory and possibly other aspects of cognition and neuropsychological function (U.S. EPA, 2012b). Neurotoxic effects have been characterized in human controlled exposure, occupational exposure and residential studies, as well as in experimental animal studies, providing evidence of an association between perchloroethylene exposure and neurological deficits (U.S. EPA, 2012b). The EPA IRIS assessment for perchloroethylene (U.S. EPA, 2012b) further notes that the nervous system is an expected target with oral perchloroethylene exposures because perchloroethylene and metabolites produced from inhalation exposures will also reach the target tissue via oral exposure.

***Kidney Toxicity***

Animal and epidemiologic evidence supports an association between perchloroethylene exposure and chronic kidney disease. Adverse effects on the kidney (e.g., kidney-to-body weight ratios, hyaline droplet formation, glomerular "nephrosis," karyomegaly (enlarged nuclei), cast formation, and other lesions or indicators of renal toxicity) have been observed in studies of rodents exposed to high concentrations of perchloroethylene by inhalation, oral and intraperitoneal (i.p.) injection of perchloroethylene metabolites, supporting the human incidence information (U.S. EPA, 2012b).

***Liver Toxicity***

Liver toxicity (i.e., necrosis, vacuolation, etc) has been reported in multiple animal species by inhalation and oral exposures to perchloroethylene, with the mouse typically being more sensitive than the rat (U.S. EPA, 2012b). The liver effects are characterized by increased liver weight, necrosis, inflammatory cell infiltration, triglyceride increases proliferation, cytoplasmic vacuolation (fatty changes), pigment in cells, oval cell hyperplasia and regenerative cellular foci. The EPA IRIS Assessment for perchloroethylene (U.S. EPA, 2012b) found suggestive evidence that perchloroethylene is a liver toxicant in humans.

***Reproductive/Developmental Toxicity***

The EPA IRIS Assessment for perchloroethylene (U.S. EPA, 2012b) evaluated the developmental and reproductive toxicity of perchloroethylene in humans and animals. Studies of tetrachloroethylene exposure in humans have evaluated several reproductive outcomes including effects on menstrual disorders, semen quality, fertility, time to pregnancy, and risk of adverse pregnancy outcomes including spontaneous abortion, low birth weight or gestational age, birth anomalies, and stillbirth (U.S. EPA, 2012b). Data from animal studies identified various manifestations of developmental toxicity including, increased mortality and decreased body weight in the offspring of rodents exposed via inhalation.

***Irritation***

Irritation data for perchloroethylene have been reviewed outside the EPA IRIS Assessment. Controlled exposures in humans and case reports have identified eye and nose irritation (NAC/AEGL, 2009).

#### 2.4.2.2 Genotoxicity and Cancer Hazards

Epidemiologic data indicate several cancer types, including non-Hodgkin lymphoma, multiple myeloma, bladder, esophageal, kidney, lung, cervical and breast cancer (U.S. EPA, 2012b). Perchloroethylene is generally considered to be non-genotoxic, however several metabolites exhibit mutagenic and/or genotoxic properties and may contribute to potential genotoxic mode of action (MOA) (U.S. EPA, 2012b). In 2012, EPA released the outcome of the weight-of-evidence cancer assessment, which described the weight-of-evidence judgment of the likelihood that perchloroethylene is a human carcinogen, and quantitative estimates of risk from oral and inhalation exposure (U.S. EPA, 2012b). Following U.S. EPA (2005a) Guidelines for Carcinogen Risk Assessment, EPA concluded that perchloroethylene is "likely to be carcinogenic in humans by all routes of exposure" (U.S. EPA, 2012b).

#### 2.4.2.3 Potentially Exposed or Susceptible Subpopulations

TSCA requires that the determination of whether a chemical substance presents an unreasonable risk include consideration of unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation" by EPA. TSCA § 3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." In developing the hazard assessment, EPA will evaluate available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s).

The EPA IRIS Assessment for perchloroethylene (U.S. EPA, 2012b) and ATSDR (2014) identified the following subpopulations as possibly more susceptible to adverse effects associated with perchloroethylene exposures: early and later lifestages and groups defined by health and nutrition status, gender, race/ethnicity, genetics and multiple exposures and cumulative risk. However EPA (2012b) also determined that the available data was insufficient to allow for a quantitative assessment of the impact of susceptibility on risk.

## 2.5 Initial Conceptual Models

A conceptual model describes the actual or predicted relationships between the chemical substance and receptors, either human or environmental. These conceptual models are integrated depictions of

the conditions of use, exposures (pathways and routes), hazards and receptors. As part of the scope for perchloroethylene, EPA developed three conceptual models, presented here.

### 2.5.1 Initial Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

Figure 2-2 presents the initial conceptual model for human receptors from industrial and commercial activities and uses of perchloroethylene. EPA expects that workers and occupational non-users may be exposed to perchloroethylene via inhalation and dermal routes. EPA also expects to consider workers' potential exposure through mists that deposit in the upper respiratory tract and are swallowed.

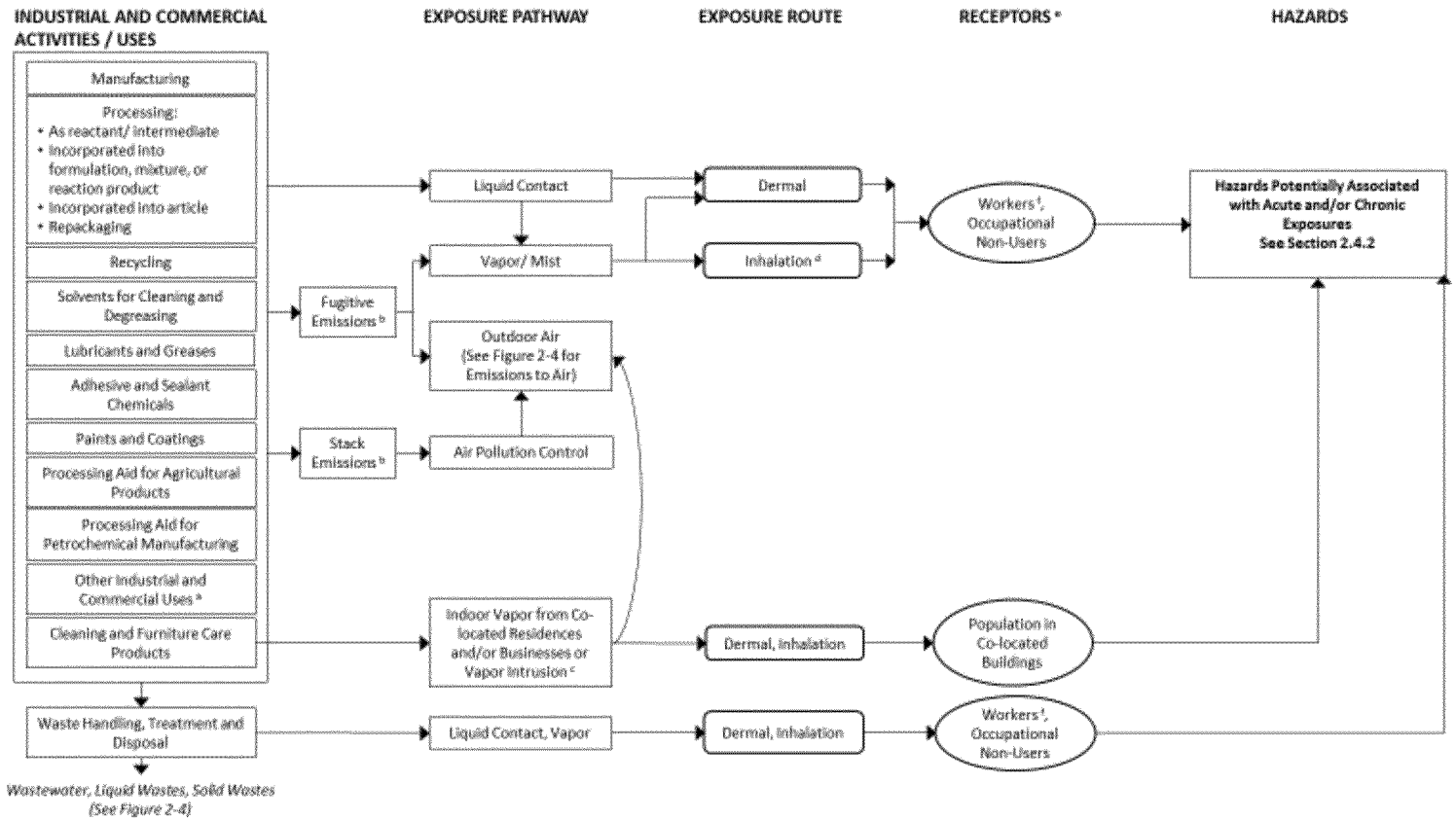


**Figure 2-2. Initial Perchloroethylene Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards**

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of perchloroethylene.

[a] Some products are used in both commercial and consumer applications. Additional uses of perchloroethylene are included in Table 2-3.

[b] Stack air emissions are emissions that occur through stacks, confined vents, ducts, pipes or other confined air streams. Fugitive air emissions are those that are not stack emissions, and include fugitive equipment leaks from valves, pump seals, flanges, compressors, sampling connections, open-ended lines; evaporative losses from surface impoundment and spills; and releases from building ventilation systems.

[c] Perchloroethylene vapor in air, soil or ground water may migrate to indoor air in co-located residences, co-located businesses or other nearby buildings.

[d] Exposure may occur through mists that deposit in the upper respiratory tract and are swallowed.

[e] Receptors include potentially exposed or susceptible subpopulations.

[f] When data and information are available to support the analysis, EPA also considers the effect that engineering controls and/or personal protective equipment have on occupational exposure levels.

### 2.5.2 Initial Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

Figure 2-3 presents the initial conceptual model for human receptors from consumer uses of perchloroethylene. Similar to Figure 2-2, consumers and bystanders may be exposed via inhalation, dermal and oral routes. It should be noted that some consumers may purchase and use products primarily intended for commercial use. It also shows emissions of perchloroethylene to wastewater, liquid and solid wastes containing perchloroethylene.

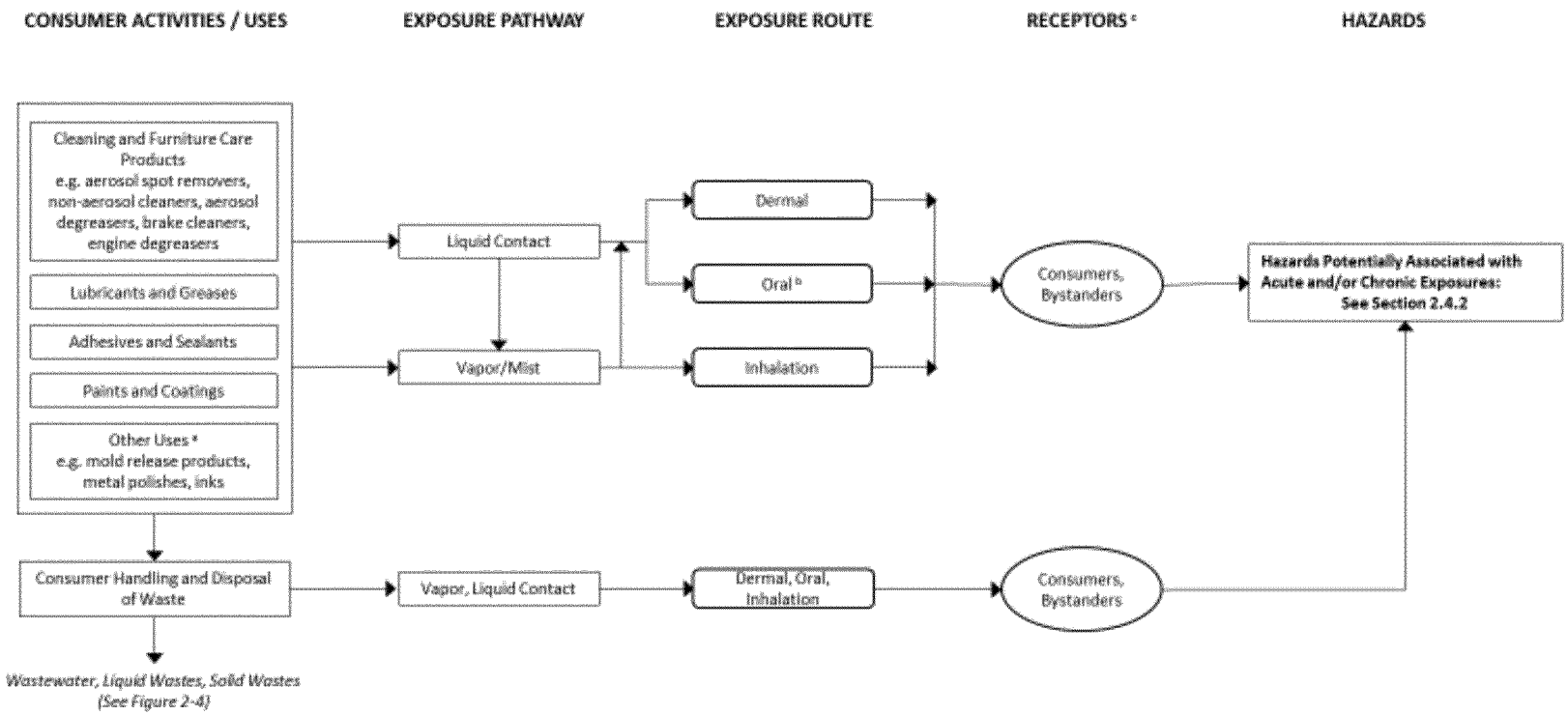


**Figure 2-3. Initial Perchloroethylene Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards**

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of perchloroethylene.

[a] Some products are used in both commercial and consumer applications. Additional uses of perchloroethylene are included in Table 2-3.

[b] Oral exposure may occur through mists that deposit in the upper respiratory tract, and are swallowed. Although less likely given the physical-chemical properties, EPA will also consider oral ingestion via oral route such as from incidental ingestion of perchloroethylene residue on hand/body.

[c] Receptors include potentially exposed or susceptible subpopulations.

### 2.5.3 Initial Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

As shown in Figure 2-4, EPA anticipates that industrial, commercial and consumer activities could result in emissions of perchloroethylene to outdoor air, as well as liquid and solid wastes containing perchloroethylene. EPA anticipates that general populations living near industrial and commercial facilities using perchloroethylene may be exposed via inhalation of outdoor air. General populations may also be exposed via ingestion of contaminated drinking water, dermal and inhalation exposure from showering/bathing with contaminated drinking water and inhalation exposure from the migration of vapor in air, soil or ground water to air. In addition, aquatic and terrestrial life may be exposed to perchloroethylene-contaminated water, sediment and soil.

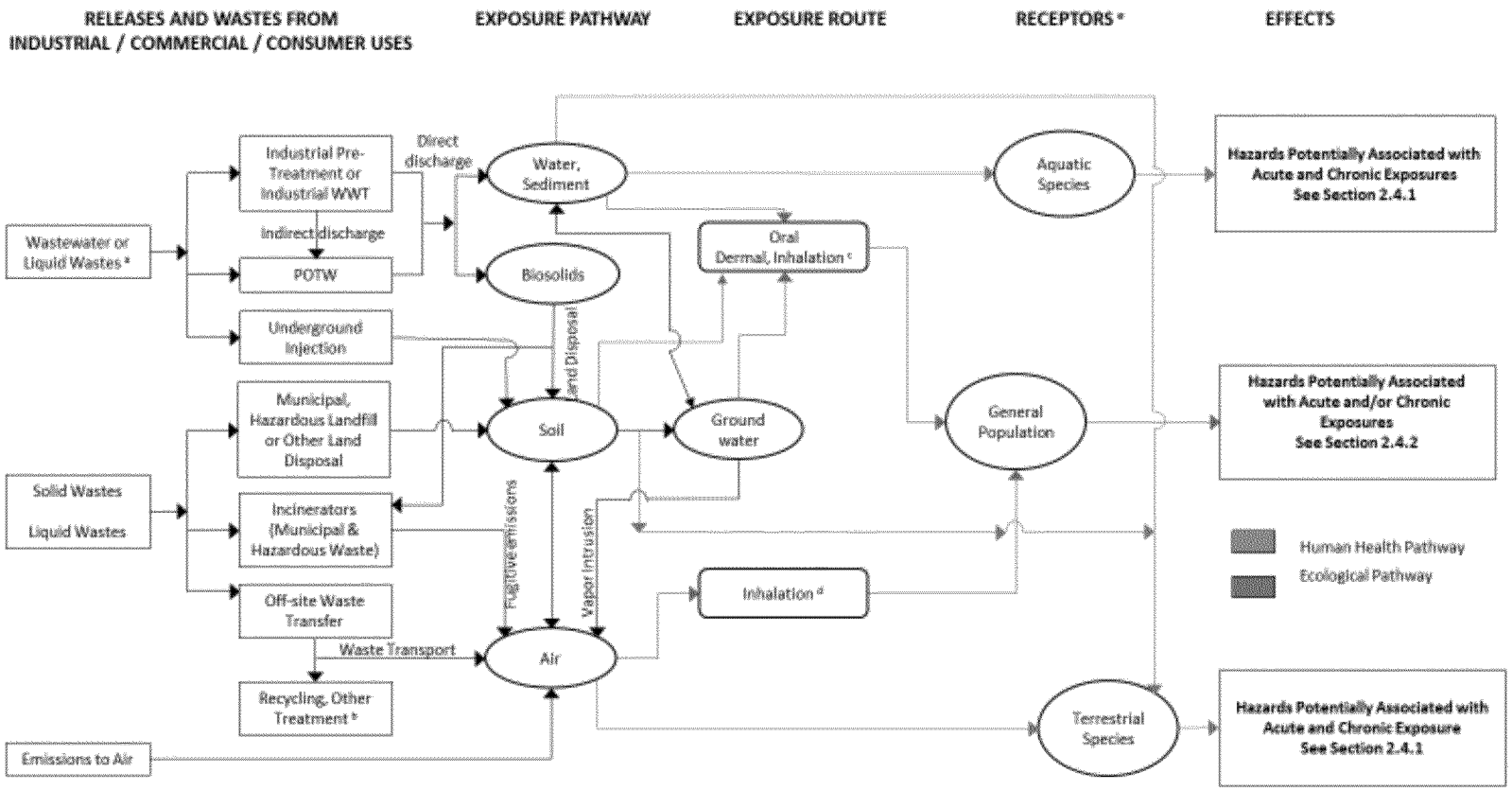


**Figure 2-4. Initial Perchloroethylene Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards**

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from environmental releases and wastes of perchloroethylene.

[a] Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge) or pre-treated and released to POTW (indirect discharge). For consumer uses, such wastes may be released directly to POTW (i.e., down the drain). Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water.

[b] Additional releases may occur from recycling and other waste treatment.

[c] Volatilization from or liquid contact with tap water in the home during showering, bathing, washing, etc. represents another potential in-home exposure pathway.

[d] Presence of mist is not expected; dermal and oral exposure are negligible.

[e] Receptors include potentially exposed or susceptible subpopulations.

## 2.6 Initial Analysis Plan

The initial analysis plan will be used to develop the eventual problem formulation and final analysis plan for the risk evaluation. While EPA has conducted a search for readily available data and information from public sources (see *Perchloroethylene (127-18-4) Bibliography: Supplemental File for the TSCA Scope Document*) as described in Section 1.3, EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources, that may be relevant for refining conditions of use, exposures, hazards and potentially exposed or susceptible subpopulations.

The analysis plan outlined here is based on the conditions of use of perchloroethylene, as described in Section 2.2 of this scope. The analysis plan may be refined as EPA proceeds with the systematic review of the information in the *Perchloroethylene (CASRN 127-18-4) Bibliography: Supplemental File for the TSCA Scope Document*. EPA will be evaluating the weight of the scientific evidence for both hazard and exposure. Consistent with this approach, EPA will also use a systematic review approach. As such, EPA will use explicit, pre-specified criteria and approaches to identify, select, assess, and summarize the findings of studies. This approach will help to ensure that the review is complete, unbiased, reproducible, and transparent.

### 2.6.1 Exposure

#### 2.6.1.1 Environmental Releases

EPA expects to consider and analyze releases to environmental media as follows:

1) Review reasonably available published literature or information on processes and activities associated with the conditions of use to evaluate the types of releases and wastes generated (*Perchloroethylene (CASRN 127-18-4) Bibliography: Supplemental File for the TSCA Scope Document)* (EPA 2017).
2) Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data collected under the TRI and National Emissions Inventory [NEI] programs).
3) Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses, volatility, chemical and physical properties.
4) Understand and consider regulatory limits that may inform estimation of environmental releases.
5) Review and determine applicability of Organisation for Economic Co-operation and Development (OECD) Emission Scenario Documents (ESDs)and EPA Generic Scenarios to estimation of environmental releases.
6) Evaluate the weight of the evidence of environmental release data.
7) Map or group each condition(s) of use to a release assessment scenario.

#### 2.6.1.2 Environmental Fate

EPA expects to consider and analyze fate and transport in environmental media as follows:

1) Review reasonably available measured or estimated environmental fate endpoint data collected through the literature search (*Perchloroethylene (CASRN 127-18-4) Bibliography: Supplemental File for the TSCA Scope Document*.
2) Using measured data and/or modeling, determine the influence of environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.

3) Evaluate the weight of the evidence of environmental fate data.

#### 2.6.1.3 Environmental Exposures

EPA expects to consider the following in developing its environmental exposure assessment of perchloroethylene:

1) Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.
2) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data. Available exposure models will be evaluated and considered alongside available monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations and soil concentrations generally consider the following inputs: release into the media of interest, fate and transport and characteristics of the environment.
3) Review reasonably available biomonitoring data. Consider whether these monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.
4) Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to extent data are available, and characterize exposed aquatic and terrestrial populations.
5) Evaluate the weight of evidence of environmental occurrence data and modeled estimates.
6) Map or group each condition(s) of use to environmental assessment scenario(s).

#### 2.6.1.4 Occupational Exposures

EPA expects to consider and analyze both worker and occupational non-user exposures as follows:

1) Review reasonably available exposure monitoring data for specific condition(s) of use. Exposure data to be reviewed may include workplace monitoring data collected by government agencies such as OSHA and the National Institute of Occupational Safety and Health (NIOSH), and monitoring data found in published literature (e.g., personal exposure monitoring data (direct measurements) and area monitoring data (indirect measurements) (*Perchloroethylene (CASRN 127-18-4) Bibliography: Supplemental File for the TSCA Scope Document)*.
2) Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to perchloroethylene.
3) For conditions of use where data limited or not available, review existing exposure models that may be applicable in estimating exposure levels.
4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.
5) Evaluate the weight of the evidence of occupational exposure data.
6) Map or group each condition of use to occupational exposure assessment scenario(s).

#### 2.6.1.5 Consumer Exposures

EPA expects to consider and analyze both consumers using a consumer product and bystanders associated with the consumer using the product as follows:

1) Review reasonably available consumer product-specific exposure data related to consumer uses/exposures.
2) Evaluate the weight of the evidence of consumer exposure data.

3) For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels.
4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.
5) Review reasonably available consumer product-specific sources to determine how those exposure estimates compare with those reported in monitoring data.
6) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further refined.
7) Map or group each condition of use to consumer exposure assessment scenario(s).

#### 2.6.1.6 General Population

EPA expects to consider and analyze general population exposures as follows:

1) Review reasonably available environmental and biological monitoring data for media to which general population exposures are expected.
2) For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels.
3) Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling.
4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.
5) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.
6) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further defined.
7) Evaluate the weight of the evidence of general population exposure data.
8) Map or group each condition of use to general population exposure assessment scenario(s).

### 2.6.2 Hazards (Effects)

#### 2.6.2.1 Environmental Hazards

EPA will conduct an environmental hazard assessment of perchloroethylene as follows:

1) Review reasonably available environmental hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies).
2) Conduct hazard identification (the qualitative process of identifying acute and chronic endpoints) and concentration-response assessment (the quantitative relationship between hazard and exposure) for all identified environmental hazard endpoints.
3) Derive concentrations of concern (COC) for all identified ecological endpoints.
4) Evaluate the weight of the evidence of environmental hazard data.
5) Consider the route(s) of exposure, available biomonitoring data and available approaches to integrate exposure and hazard assessments.

#### 2.6.2.2 Human Health Hazards

EPA expects to consider and analyze human health hazards as follows:

1) Review reasonably available human health hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies; systems biology.
2) In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.
3) Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for all identified human health hazard endpoints.
4) Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling depending on the available data. Adjust the PODs as appropriate to conform (e.g., adjust for duration of exposure) to the specific exposure scenarios evaluated.
5) Evaluate the weight of the evidence of human health hazard data.
6) Consider the route(s) of exposure (oral, inhalation, dermal), available route-to-route extrapolation approaches, available biomonitoring data and available approaches to correlate internal and external exposures to integrate exposure and hazard assessment.

### 2.6.3 Risk Characterization

Risk characterization is an integral component of the risk assessment process for both ecological and human health risks. EPA will derive the risk characterization in accordance with EPA's *Risk Characterization Handbook* (U.S. EPA, 2000a). As defined in EPA's *Risk Characterization Policy*, "the risk characterization integrates information from the preceding components of the risk evaluation and synthesizes an overall conclusion about risk that is complete, informative and useful for decision makers." Risk characterization is considered to be a conscious and deliberate process to bring all important considerations about risk, not only the likelihood of the risk, but also the strengths and limitations of the assessment, and a description of how others have assessed the risk into an integrated picture.

Risk characterization at EPA assumes different levels of complexity depending on the nature of the risk assessment being characterized. The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. Regardless of the level of complexity or information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is transparent, clear, consistent and reasonable (TCCR) (U.S. EPA, 2000a). EPA will also present information in this section consistent with approaches described in the Risk Evaluation Framework Rule.

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# APPENDICES

# Appendix A REGULATORY HISTORY

## A.1 Federal Laws and Regulations

**Table_Apx A-1. Federal Laws and Regulations**

| Statutes/Regulations | Description of Authority/Regulation | Description of Regulation |
|---|---|---|
| **EPA Regulations** | | |
| Toxics Substances Control Act (TSCA) – Section 6(b) | EPA is directed to identify and begin risk evaluations on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments. | Perchloroethylene is on the initial list of chemicals to be evaluated for unreasonable risk under TSCA (81 FR 91927, December 19, 2016). |
| Toxics Substances Control Act (TSCA) – Section 8(a) | The TSCA section 8(a) Chemical Data Reporting (CDR) Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States. | Perchloroethylene manufacturing (including importing), processing, and use information is reported under the Chemical Data Reporting (CDR) rule (76 FR 50816, August 16, 2011). |
| Toxics Substances Control Act (TSCA) – Section 8(b) | EPA must compile, keep current, and publish a list (the TSCA Inventory) of each chemical substance manufactured, processed or imported in the United States. | Perchloroethylene was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process (76 FR 50816, August 16, 2011). |
| Toxics Substances Control Act (TSCA) – Section 8(e) | Manufacturers (including imports), processors, and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment. | Eleven risk reports received for perchloroethylene (1978-2010) (US EPA, ChemView. Accessed April 13, 2017). |

| Statutes/Regulations | Description of Authority/Regulation | Description of Regulation |
|---|---|---|
| Toxics Substances Control Act (TSCA) – Section 4 | Provides EPA with authority to issue rules and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures. | Nine chemical data submissions from test rules received for perchloroethylene (1978-1980) (US EPA, ChemView. Accessed April 13, 2017). |
| Emergency Planning and Community Right-to-Know Act (EPCRA) – Section 313 | Requires annual reporting from facilities in specific industry sectors that employ 10 or more full time equivalent employees and that manufacture, process or otherwise use a TRI-listed chemical in quantities above threshold levels. | Perchloroethylene is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 1, 1987. |
| Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) - Sections 3 and 6 | FIFRA governs the sale, distribution and use of pesticides. Section 3 of FIFRA generally requires that pesticide products be registered by EPA prior to distribution or sale. Pesticides may only be registered if, among other things, they do not cause "unreasonable adverse effects on the environment." Section 6 of FIFRA provides EPA with the authority to cancel pesticide registrations if either (1) the pesticide, labeling or other material does not comply with FIFRA; or (2) when used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment. | EPA removed perchloroethylene and other chemical substances from its list of pesticide product inert ingredients used in pesticide products (63 FR 34384, June 24, 1998). |
| Clean Air Act (CAA) – Section 112(b) | Defines the original list of 189 hazardous air pollutants (HAP). Under 112(c) of the | Lists perchloroethylene as a Hazardous Air Pollutant (42 U.S. Code § 7412), and is |

| Statutes/Regulations | Description of Authority/Regulation | Description of Regulation |
|---|---|---|
| | CAA, EPA must identify and list source categories that emit HAP and then set emission standards for those listed source categories under CAA section 112(d). CAA section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAP by adding or deleting a substance. Since 1990 EPA has removed two pollutants from the original list leaving 187 at present. | considered an "urban air toxic" (CAA Section 112(k)). |
| Clean Air Act (CAA) – Section 112(d) | Section 112(d) states that the EPA must establish national emission standards for HAP (NESHAP) for each category or subcategory of major sources and area sources of HAPs [listed pursuant to Section 112(c)]. The standards must require the maximum degree of emission reduction that the EPA determines to be achievable by each particular source category. Different criteria for maximum achievable control technology (MACT) apply for new and existing sources. Less stringent standards, known as generally available control technology (GACT) standards, are allowed at the Administrator's discretion for area sources. | There are a number of source-specific CAA, Section 112, NESHAPs for perchloroethylene, including:<br>Dry cleaners (73 FR 39871, July 11, 2008)<br>Organic liquids distribution (non-gasoline) (69 FR 5038, February 3, 2004)<br>Off-site waste and recovery operations (64 FR 38950, July 20, 1999)<br>Rubber Tire Manufacturing (67 FR 45588, July 9, 2002)<br>Wood furniture manufacturing (60 FR 62930, December 7, 1995)<br>Synthetic organic chemical manufacturing (59 FR 19402, April 22,1994)<br>Chemical Manufacturing Area Source Categories (74 FR 56008, October 29, 2009)<br>Publicly Owned Treatment Works (64 FR 57572, October 26, 1999)<br>Site Remediation includes perchloroethylene (68 FR 58172, October 8, 2003) |

| Statutes/Regulations | Description of Authority/Regulation | Description of Regulation |
|---|---|---|
| Clean Air Act (CAA) – Section 183(e) | Section 183(e) requires EPA to list the categories of consumer and commercial products that account for at least 80 percent of all VOC emissions in areas that violate the National Ambient Air Quality Standards (NAAQS) for ozone and to issue standards for these categories that require "best available controls." In lieu of regulations, EPA may issue control techniques guidelines if the guidelines are determined to be substantially as effective as regulations. | Perchloroethylene is listed under the National Volatile Organic Compound Emission Standards for Aerosol Coatings (40 CFR part 59, subpart E). Perchloroethylene has a reactivity factor of 0.04g O3/g VOC. |
| Clean Air Act (CAA) – Section 612 | Under Section 612 of the Clean Air Act (CAA), EPA's Significant New Alternatives Policy (SNAP) program reviews substitutes for ozone depleting substances within a comparative risk framework. EPA publishes lists of acceptable and unacceptable alternatives. A determination that an alternative is unacceptable or acceptable only with conditions, is made through rulemaking. | Under the SNAP program, EPA listed perchloroethylene as an acceptable substitute in cleaning solvent for metal cleaning, electronics cleaning and precision cleaning (59 FR 13044, March 18, 1994). Perchloroethylene is cited as an alternative to methyl chloroform and CFC-113 for metals, electronics and precision cleaning. Perchloroethylene was also noted to have no ozone depletion potential and cited as a VOC-exempt solvent and acceptable ozone-depleting substance substitute (72 FR 30142, May 30, 2007). |
| Clean Water Act (CWA) – Section 301(b), 304(b), 306, and 307(b) | Requires establishment of Effluent Limitations Guidelines and Standards for conventional, toxic, and non-conventional pollutants. For toxic and non-conventional pollutants, EPA | Perchloroethylene is designated as a toxic pollutant under section 307(a)(1) of CWA and as such is subject to effluent limitations. Also under section 304, perchloroethylene is |

| Statutes/Regulations | Description of Authority/Regulation | Description of Regulation |
|---|---|---|
| | identifies the best available technology that is economically achievable for that industry after considering statutorily prescribed factors and sets regulatory requirements based on the performance of that technology. | included in the list of total toxic organics (TTO) (40 CFR 413.02(i)). |
| Clean Water Act (CWA) – Section 307(a) | Establishes a list of toxic pollutants or combination of pollutants under the CWA. The statute specifies a list of families of toxic pollutants also listed in the Code of Federal Regulations at 40 CFR 401.15. The "priority pollutants" specified by those families are listed in 40 CFR part 423, Appendix A. These are pollutants for which best available technology effluent limitations must be established on either a national basis through rules (Sections 301(b), 304(b), 307(b), 306), or on a case-by-case best professional judgement basis in NPDES permits (Section 402(a)(1)(B)). | |
| Safe Drinking Water Act (SDWA) – Section 1412 | Requires EPA to publish a non-enforceable maximum contaminant level goals (MCLGs) for contaminants which 1. may have an adverse effect on the health of persons; 2. are known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of | Perchloroethylene is subject to National Primary Drinking Water Regulations (NPDWR) under SDWA with a MCLG of zero and an enforceable maximum contaminant level (MCL) of 0.005 mg/L (40 CFR 141.61). On January 11, 2017, EPA announced a review of the eight existing NPDWRs (82 FR 3518). Perchloroethylene is one of |

| Statutes/Regulations | Description of Authority/Regulation | Description of Regulation |
|---|---|---|
| | public health concern; and 3. in the sole judgment of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems. When EPA publishes an MCLG, EPA must also promulgate a National Primary Drinking Water Regulation (NPDWR) which includes either an enforceable maximum contaminant level (MCL) or a required treatment technique. Public water systems are required to comply with NPDWRs | the eight NPDWRs. EPA requested comment on the eight NPDWRs identified as candidates for revision. |
| Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) – Section 102(a) and 103 | Authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103.<br><br>Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold. | Perchloroethylene is a hazardous substance under CERCLA. Releases of perchloroethylene in excess of 100 pounds must be reported (40 CFR 302.4). |

| Statutes/Regulations | Description of Authority/Regulation | Description of Regulation |
|---|---|---|
| Resource Conservation and Recovery Act (RCRA) – Section 3001 | Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics. | Perchloroethylene is included on the list of hazardous wastes pursuant to RCRA 3001.<br><br>In 2013, EPA modified its hazardous waste management regulations to conditionally exclude solvent-contaminated wipes that have been cleaned and reused from the definition of solid waste under RCRA (78 FR 46447, July 31, 2013). RCRA Hazardous Waste Code: D039 at 0.7 mg/L; F001, F002; U210. |
| Superfund Amendments and Reauthorization Act (SARA) – | Requires the Agency to revise the hazardous ranking system and update the National Priorities List of hazardous waste sites, increases state and citizen involvement in the superfund program and provides new enforcement authorities and settlement tools. | Perchloroethylene is listed on SARA, an amendment to CERCLA and the CERCLA Priority List of Hazardous Substances. This list includes substances most commonly found at facilities on the CERCLA National Priorities List (NPL) that have been deemed to pose the greatest threat to public health. |
| **Other Federal Regulations** | | |
| Federal Hazardous Substance Act (FHSA) | Allows the Consumer Product Safety Commission (CPSC) to (1) require precautionary labeling on the immediate container of hazardous household products or (2) to ban certain products that are so dangerous or the nature of the hazard is such that required labeling is not adequate to protect consumers. | Under the Federal Hazardous Substance Act, section 1500.83(a)(31), visual novelty devices containing perchloroethylene are regulated by CPSC. |

| Statutes/Regulations | Description of Authority/Regulation | Description of Regulation |
|---|---|---|
| Federal Food, Drug, and Cosmetic Act (FFDCA) | Provides the U.S. FDA (Food and Drug Administration) with authority to oversee the safety of food, drugs and cosmetics. | The FDA regulates perchloroethylene in bottled water. The maximum permissible level of perchloroethylene in bottled water is 0.005 mg/L (21 CFR 165.110). |
| Occupational Safety and Health Act (OSH Act) | Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress or unsanitary conditions. Under the Act, the Occupational Safety and Health Administration can issue occupational safety and health standards including such provisions as Permissible Exposure Limits (PELs), exposure monitoring, engineering and administrative control measures and respiratory protection. | In 1970, OSHA issued occupational safety and health standards for perchloroethylene that included a Permissible Exposure Limit (PEL) of 100 ppm TWA, exposure monitoring, control measures and respiratory protection (29 CFR 1910.1000). |
| Atomic Energy Act Department of Energy (DOE) | The Atomic Energy Act authorizes DOE to regulate the health and safety of its contractor employees | 10 CFR 851.23, Worker Safety and Health Program, requires the use of the 2005 ACGIH TLVs if they are more protective than the OSHA PEL. The 2005 TLV for perchloroethylene is 25 ppm (8hr Time Weighted Average) and 100 ppm Short Term Exposure Limit(STEL). |

## A.2 State Laws and Regulations

**Table_Apx A-2. State Laws and Regulations**

| State Actions | Description of Action |
|---|---|
| **State actions** | |
| State Permissible Exposure Limits | California has a workplace PEL of 25 ppm (California, OEHHA, 1988) |
| State Right-to-Know Acts | Massachusetts (454 CMR 21.00), New Jersey (42 N.J.R 1709(a)), Pennsylvania (Chapter 323, Hazardous Substance List), Rhode Island (RI Gen. Laws Sec. 28-21-1et seq). |
| Volatile Organic Compound (VOC) Regulations for Consumer Products | Many states regulate perchloroethylene as a VOC. These regulations may set VOC limits for consumer products and/or ban the sale of certain consumer products as an ingredient and/or impurity. Regulated products vary from state to state, and could include contact and aerosol adhesives, aerosols, electronic cleaners, footwear or leather care products, and general degreasers, among other products. California (Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 8.5, Articles 1, 2, 3 and 4), Connecticut (R.C.S.A Sections 22a-174-40, 22a-174-41, and 22a-174-44), Delaware (Adm. Code Title 7, 1141), District of Columbia (Rules 20-720, 20-721, 20-735, 20-736, 20-737), Illinois (35 Adm Code 223), Indiana ( 326 IAC 8-15), Maine (Chapter 152 of the Maine Department of Environmental Protection Regulations), Maryland (COMAR 26.11.32.00 to 26.11.32.26), Michigan (R 336.1660 and R 336. 1661), New Hampshire (Env-A 4100) New Jersey (Title 7, Chapter 27, Subchapter 24), New York (6 CRR-NY III A 235), Rhode Island (Air Pollution Control Regulation No. 31), and Virginia (9VAC5 CHAPTER 45) all have VOC regulations or limits for consumer products. Some of these states also require emissions reporting. |
| Other | There are several state level NESHAPs for dry cleaning and restrictions or phase outs of perchloroethylene (e.g. California, Maine, Massachusetts). Numerous states list perchloroethylene on a list of chemical substances of high concern to children (e.g. Oregon, Vermont, Washington). Under the California Proposition 65 list (California OEHHA), perchloroethylene is known to the state of California to cause cancer. |

## A.3 International Laws and Regulations

**Table_Apx A-3. Regulatory Actions by Other Governments and Tribes**

| Country/Organization | Requirements and Restrictions |
|---|---|
| Canada | Perchloroethylene is on the Canadian List of Toxic Substances (CEPA 1999 Schedule 1). The use and sale of perchloroethylene in the dry cleaning industry is regulated under *Use in Dry Cleaning and Reporting Requirements Regulations (Canada Gazette*, Part II on March 12, 2003. Perchloroethylene is also regulated for use and sale for solvent degreasing under Solvent Degreasing Regulations (SOR/2003-283) (Canada Gazette, Part II on August 13, 2003). The purpose of the regulation is to reduce releases of perchloroethylene into the environment from solvent degreasing facilities using more than 1,000 kilograms of perchloroethylene per year. The regulation includes a market intervention by establishing tradable allowances for the use of perchloroethylene in solvent degreasing operations that exceed the 1,000 kilograms threshold per year. |
| European Union | Perchloroethylene was evaluated under the 2013 Community Rolling Action Plan (CoRAP). The conclusion was no additional regulatory action was required (European Chemicals Agency (ECHA) database. Accessed April, 18 2017). |
| Australia | In 2011, a preliminary assessment of perchloroethylene was conducted (National Industrial Chemicals Notification and Assessment Scheme, NICNAS, 2016, Tetrachloroethylene. Accessed April, 18 2017). |
| Japan | Perchloroethylene is regulated in Japan under the following legislation:<br>• Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL)<br>• Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof<br>• Industrial Safety and Health Act (ISHA)<br>• Air Pollution Control Law<br>• Water Pollution Control Law<br>• Soil Contamination Countermeasures Act<br>• Law for the Control of Household Products Containing Harmful Substances<br>(National Institute of Technology and Evaluation (NITE) Chemical Risk Information Platform (CHIRP). Accessed April 18, 2017) |
| Australia, Austria, Belgium, Canada, Denmark, European Union, Finland, France, Germany, Hungary, Ireland, Israel, Japan, | Occupational exposure limits for perchloroethylene (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed April 18, 2017). |

| Country/Organization | Requirements and Restrictions |
|---|---|
| Latvia, New Zealand, People's Republic of China, Poland, Singapore, South Korea, Spain, Sweden, Switzerland, United Kingdom | |
| Basel Convention | Halogenated organic solvents (Y41) are listed as a category of waste under the Basel Convention – Annex I. Although the United States is not currently a party to the Basel Convention, this treaty still affects U.S. importers and exporters. |
| OECD Control of Transboundary Movements of Wastes Destined for Recovery Operations | Halogenated organic solvents (A3150) are listed as a category of waste subject to The Amber Control Procedure under Council Decision C (2001) 107/Final. |

# Appendix B PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found in preliminary data gathering for perchloroethylene.

## B.1 Process Information

Process-related information potentially relevant to the risk evaluation may include process diagrams, descriptions and equipment. Such information may inform potential release sources and worker exposure activities for consideration. The following subsections provide process descriptions based on cursory review of several sources identified from the preliminary literature search. EPA will continue to review and further refine the descriptions for each life cycle stage throughout the risk evaluation process.

### B.1.1 Manufacture (Including Import)

Perchloroethylene was previously produced through chlorination of acetylene to tetrachloroethane, then dehydrochlorination to trichloroethylene (TCE), followed by chlorination of TCE to pentachloroethane and finally dehydrochlorination to perchloroethylene (Snedecor et al., 2004). The last U.S. plant using the acetylene process was shut down in 1978 (Snedecor et al., 2004). Currently, most perchloroethylene is manufactured using one of three methods: chlorination of ethylene dichloride (EDC); chlorination of hydrocarbons containing one to three carbons (C1 to C3) or their partially chlorinated derivatives; or oxychlorination of two-carbon (C2) chlorinated hydrocarbons (ATSDR, 2014; Snedecor et al., 2004; U.S. EPA, 1985b).

**Chlorination of EDC –** The chlorination of EDC involves a non-catalytic reaction of chlorine and EDC or other C2 chlorinated hydrocarbons to form perchloroethylene and TCE as co-products and hydrochloric acid (HCl) as a byproduct (ATSDR, 2014; Snedecor et al., 2004; U.S. EPA, 1985b). Following reaction, the product undergoes quenching, HCl separation, neutralization, drying and distillation (U.S. EPA, 1985b).

**Chlorination of C1-C3 hydrocarbons –** The chlorination of C1-C3 hydrocarbons involves the reaction of chlorine with a hydrocarbon such as methane, ethane, propane, propylene or their chlorinated derivatives, at high temperatures (550–700°C), with or without a catalyst, to form perchloroethylene and carbon tetrachloride ($CCl_4$) as co-products and HCl as a byproduct (ATSDR, 2014; Snedecor et al., 2004; U.S. EPA, 1985b). Due to phase-out of CFC-11 and CFC-12 and most $CCl_4$ uses, most facilities using this method maximize the production of perchloroethylene and minimize or eliminate the production of $CCl_4$ (Snedecor et al., 2004).

**Oxychlorination of C2 chlorinated hydrocarbons –** The oxychlorination of C2 chlorinated hydrocarbons involves the reaction of either chlorine or HCl and oxygen with EDC in the presence of a catalyst to produce perchloroethylene and TCE as co-products (ATSDR, 2014; Snedecor et al., 2004). Following reaction, the product undergoes HCl separation, drying, distillation, neutralization with ammonia and a final drying step (U.S. EPA, 1985b).

In all three processes the product ratio of perchloroethylene to TCE/$CCl_4$ products are controlled by adjusting the reactant ratios (Snedecor et al., 2004).

According to Snedecor et al. (2004), perchloroethylene may be shipped by barge, tank car, tank truck or 55-gallon steel drums. Perchloroethylene may be stored in steel tanks that are dry, free of rust and equipped with a chemical vent dryer and controlled evaporation vent (Snedecor et al., 2004).

#### B.1.1.1 Domestic Manufacture

Perchloroethylene was previously produced through chlorination of acetylene to tetrachloroethane, then dehydrochlorination to TCE, followed by chlorination of TCE to pentachlorethane and finally dehydrochlorination to perchloroethylene (Snedecor et al., 2004). The last U.S. plant using the acetylene process was shut down in 1978 (Snedecor et al., 2004). Currently, most perchloroethylene is manufactured using one of three methods: chlorination of EDC; chlorination of hydrocarbons containing one to three carbons (C1 to C3) or their partially chlorinated derivatives; or oxychlorination of two-carbon (C2) chlorinated hydrocarbons (ATSDR, 2014; Snedecor et al., 2004; U.S. EPA, 1985b).

- Chlorination of EDC – The chlorination of EDC involves a noncatalytic reaction of chlorine and EDC or other C2 chlorinated hydrocarbons to form perchloroethylene and TCE as co-products and HCl as a byproduct (ATSDR, 2014; Snedecor et al., 2004; U.S. EPA, 1985b). Following reaction, the product undergoes quenching, HCl separation, neutralization, drying and distillation (U.S. EPA, 1985b). This process is advantageous at facilities that have a feedstock source of mixed C2 chlorinated hydrocarbons from other processes and an outlet for the HCl byproduct (Snedecor et al., 2004).
- Chlorination of C1-C3 hydrocarbons – The chlorination of C1-C3 hydrocarbons involves the reaction of chlorine with a hydrocarbon such as methane, ethane, propane, propylene or their chlorinated derivatives, at high temperatures (550–700°C), with or without a catalyst, to form perchloroethylene and $CCl_4$ as co-products and HCl as a byproduct (ATSDR, 2014; Snedecor et al., 2004; U.S. EPA, 1985b). This process is advantageous because mixed chlorinated hydrocarbon wastes from other processes can be used as a feedstock (ATSDR, 2014; Snedecor et al., 2004). Due to phase-out of CFC-11 and CFC-12 and most $CCl_4$ uses, most facilities using this method maximize the production of perchloroethylene and minimize or eliminate the production of $CCl_4$ (Snedecor et al., 2004).
- Oxychlorination of C2 chlorinated hydrocarbons – The oxychlorination of C2 chlorinated hydrocarbons involves the reaction of either chlorine or HCl and oxygen with EDC in the presence of a catalyst to produce perchloroethylene and TCE as co-products (ATSDR, 2014; Snedecor et al., 2004). Following reaction, the product undergoes HCl separation, drying, distillation and neutralization with ammonia, and a final drying step (U.S. EPA, 1985b). The advantage of this process is that no byproduct HCl is produced and can be combined with other processes as a net HCl consumer (ATSDR, 2014; Snedecor et al., 2004).

In all three processes the product ratio of perchloroethylene to TCE/$CCl_4$ products are controlled by adjusting the reactant ratios (Snedecor et al., 2004).

#### B.1.1.2 Import

According to Snedecor et al. (2004), perchloroethylene may be shipped by barge, tank car, tank truck or 55-gallon steel drums. Perchloroethylene may be stored in steel tanks that are dry, free of rust and equipped with a chemical vent dryer and controlled evaporation vent (Snedecor et al., 2004).

## B.1.2 Processing and Distribution

### B.1.2.1 Reactant or Intermediate

Processing as a reactant or intermediate is the use of perchloroethylene as a feedstock in the production of another chemical product via a chemical reaction in which perchloroethylene is consumed to form the product. In the past, perchloroethylene was used as feedstock (with chlorine) for the manufacture of one- and two-carbon (C1 and C2) CFCs (Smart and Fernandez, 2000). However, due to discovery that CFCs contribute to stratospheric ozone depletion, the use of CFCs was phased-out by the year 2000 to comply with the Montreal Protocol (Smart and Fernandez, 2000). Since the phase-out of CFCs, perchloroethylene has been used to manufacture the CFC alternatives, HCFCs, specifically the HCFC-123 alternative to CFC-11 (Smart and Fernandez, 2000). Perchloroethylene is also used as a feedstock in the production of trichloroacetyl chloride (Smart and Fernandez, 2000).

HCFC-123 is produced by fluorination of perchloroethylene with liquid or gaseous hydrofluoric acid (HF). The manufacture of HCFC is more complex than the manufacture of CFCs due to potential byproduct formation or catalyst inactivation caused by the extra hydrogen atom in the HCFCs (Smart and Fernandez, 2000). Therefore, the process involved in the manufacture of HCFCs requires additional reaction and distillation steps as compared to the CFC manufacturing process (Smart and Fernandez, 2000).

### B.1.2.2 Incorporating into a Formulation, Mixture or Reaction Product

Incorporation into a formulation, mixture or reaction product refers to the process of mixing or blending of several raw materials to obtain a single product or preparation. The uses of perchloroethylene that may require incorporation into a formulation include adhesives, sealants, coatings, inks, lubricants and plastic and rubber manufacturing. Perchloroethylene specific formulation processes were not identified; however, several ESDs published by the OECD and Generic Scenarios published by EPA have been identified that provide general process descriptions for these types of products.

The formulation of coatings and inks typically involves dispersion, milling, finishing and filling into final packages (OECD, 2009c; U.S. EPA, 2001). Adhesive formulation involves mixing together volatile and non-volatile chemical components in sealed, unsealed or heated processes (OECD, 2009a). Sealed processes are most common for adhesive formulation because many adhesives are designed to set or react when exposed to ambient conditions (OECD, 2009a). Lubricant formulation typically involves the blending of two or more components, including liquid and solid additives, together in a blending vessel (OECD, 2004). In plastics and rubber manufacturing the formulation step usually involves the compounding of the polymer resin with additives and other raw materials to form a masterbatch in either open or closed blending processes (U.S. EPA, 2014b; OECD, 2009b). After compounding, the resin is fed to an extruder where is it converted into pellets, sheets, films or pipes (U.S. EPA, 2014b).

### B.1.2.3 Incorporating into an Article

Incorporation into an article typically refers to a process in which a chemical becomes an integral component of an article (as defined at 40 CFR 704.3) that is distributed for industrial, trade or consumer use. The use of perchloroethylene in plastic and rubber manufacturing is the only use that would incorporate perchloroethylene into an article. An ESD published by the OECD and one generic scenario published by EPA were identified that include general process descriptions for the formation of plastic articles.

In plastic manufacturing, the final plastic article is produced in a conversion process that forms the compounded plastic into the finished products (U.S. EPA, 2014c; OECD, 2009b). The converting process is different depending on whether the plastic is a thermoplastic or a thermosetting material (OECD, 2009b). Thermoplastics converting involves the melting of the plastic material, forming it into a new shape and then cooling it (U.S. EPA, 2014c; OECD, 2009b). The converting of thermoplastics may involve extrusion, injection molding, blow molding, rotational molding or thermoforming (U.S. EPA, 2014c; OECD, 2009b).

Conversion of thermosetting materials involves using heat and pressure to promote curing, typically through cross-linking (OECD, 2009b). The primary conversion process for thermosetting materials is compression molding; however, fiber reinforced thermosetting plastics are converted using hand layup, spray molding and filament winding (OECD, 2009b). After the forming process, finishing operations such as filing, grinding, sanding, polishing, painting, bonding, coating and engraving are performed to complete the process (U.S. EPA, 2014c).

#### B.1.2.4 Repackaging

Typical repackaging sites receive the chemical in bulk containers and transfer the chemical from the bulk container into another smaller container in preparation for distribution in commerce.

#### B.1.2.5 Recycling

Waste perchloroethylene solvent is generated when it becomes contaminated with suspended and dissolved solids, organics, water or other substance (U.S. EPA, 1980b). Waste solvents can be restored to a condition that permits reuse via solvent reclamation/recycling (U.S. EPA, 1985b, 1980b). Waste perchloroethylene is shopped to a solvent recovery site where it is piped or manually loaded into process equipment (U.S. EPA, 1985b). The waste solvent then undergoes a vapor recovery (e.g., condensation, adsorption and absorption) or mechanical separation (e.g., decanting, filtering, draining, setline and centrifuging) step followed by distillation, purification and final packaging (U.S. EPA, 1985b, 1980b).

### B.1.3 Uses

In this document, EPA has grouped uses based on CDR categories, and identified examples within these categories as subcategories of use. Note that some subcategories of use may be grouped under multiple CDR categories. The differences between these uses will be further investigated and defined later during risk evaluation.

#### B.1.3.1 Cleaning and Furniture Care Products

The "Cleaning and Furniture Care Products" category encompasses chemical substances contained in products that are used to remove dirt, grease, stains and foreign matter from furniture and furnishings or to cleanse, sanitize, bleach, scour, polish, protect or improve the appearance of surfaces. Products designed to clean wood floors or other substrates which contain methylene chloride are used in industrial or commercial settings and are primarily formulated as liquids.

**Dry Cleaning Solvent and Spot Cleaner**

Perchloroethylene can be used as a solvent in dry cleaning machines and is found in products used to spot clean garments. Spot cleaning products can be applied to the garment either before or after the garment is dry cleaned. The process and worker activities associated with commercial dry cleaning and

spot cleaning have been previously described in EPA's 1-Bromopropane (1-BP) Draft Risk Assessment (U.S. EPA, 2016c). Note: The 1-BP risk assessment focuses on use at commercial dry cleaning facilities; however, according to EPA's *Economic Impact Analysis of the Final Perchloroethylene Dry Cleaning Residual Risk Standard* (2006a), there are seven industrial dry cleaners that use perchloroethylene. Industrial dry cleaners clean heavily stained articles such as work gloves, uniforms, mechanics' overalls, mops and shop rags (U.S. EPA, 2006a). The general worker activities at industrial dry cleaners are not expected to significantly differ from activities at commercial dry cleaners.

**Non-Aerosol Degreasers and Cleaners**

Perchloroethylene can also be used as a solvent in non-aerosol degreasing and cleaning products. Non-aerosol cleaning products typically involve dabbing or soaking a rag with cleaning solution and then using the rag to wipe down surfaces or parts to remove contamination (U.S. EPA, 2014a). The cleaning solvent is usually applied in excess and allowed to air-dry (U.S. EPA, 2014a). Parts may be cleaned in place or removed from the service item for more thorough cleaning (U.S. EPA, 2014a).

**Aerosol Spray Degreasers and Cleaners**

Aerosol degreasing is a process that uses an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from fabricated parts. Products containing perchloroethylene may be used in aerosol degreasing applications such as brake cleaning, engine degreasing and metal product cleaning. This use has been previously described in EPA's 1-BP Draft Risk Assessment (2016c). Aerosol degreasing may occur at either industrial facilities or at commercial repair shops to remove contaminants on items being serviced. Aerosol degreasing products may also be purchased and used by consumers for various applications.

### B.1.3.2 Solvents for Cleaning and Degreasing

EPA has gathered information on different types of cleaning and degreasing systems from recent TCE risk assessment (U.S. EPA, 2014d) and risk management activities (FR 81(242): 91592-91624. December 16, 2016, and FR 82(12): 7432-7461. January 19, 2017) and 1-BP risk assessment (U.S. EPA, 2016c) activities. Provided below are descriptions of five cleaning and degreasing uses of perchloroethylene.

***Vapor Degreasers***

Vapor degreasing is a process used to remove dirt, grease and surface contaminants in a variety of metal cleaning industries. Vapor degreasing may take place in batches or as part of an in-line (i.e., continuous) system. Vapor degreasing equipment can generally be categorized into one of three degreaser types described below:

**Batch vapor degreasers:** In batch machines, each load (parts or baskets of parts) is loaded into the machine after the previous load is completed. Individual organizations, regulations and academic studies have classified batch vapor degreasers differently. For the purposes of the scope document, EPA categories the batch vapor degreasers into five types: open top vapor degreasers (OTVDs); OTVDs with enclosures; closed-loop degreasing systems (airtight); airless degreasing systems (vacuum drying); and airless vacuum-to-vacuum degreasing systems.

**Conveyorized vapor degreasers:** In conveyorized systems, an automated parts handling system, typically a conveyor, continuously loads parts into and through the vapor degreasing equipment and the subsequent drying steps. Conveyorized degreasing systems are usually fully enclosed except for the

conveyor inlet and outlet portals. Conveyorized degreasers are likely used in shops where there are a large number of parts being cleaned. There are seven major types of conveyorized degreasers: monorail degreasers; cross-rod degreasers; vibra degreasers; ferris wheel degreasers; belt degreasers; strip degreasers; and circuit board degreasers (U.S. EPA, 1977).

**Continuous web vapor degreasers:** Continuous web cleaning machines are a subset of conveyorized degreasers but differ in that they are specifically designed for cleaning parts that are coiled or on spools such as films, wires and metal strips (Kanegsberg and Kanegsberg, 2011; U.S. EPA, 2006c). In continuous web degreasers, parts are uncoiled and loaded onto rollers that transport the parts through the cleaning and drying zones at speeds greater than 11 feet per minute (U.S. EPA, 2006c). The parts are then recoiled or cut after exiting the cleaning machine (Kanegsberg and Kanegsberg, 2011; U.S. EPA, 2006c).

***Cold Cleaners***

Perchloroethylene can also be used as a solvent in cold cleaners, which are non-boiling solvent degreasing units. Cold cleaning operations include spraying, brushing, flushing and immersion; the use process and worker activities associated with cold cleaning have been previously described in EPA's 1-BP Draft Risk Assessment (U.S. EPA, 2016c).

***Non-Aerosol Degreasers and Cleaners***

Perchloroethylene can also be used as a solvent in non-aerosol degreasing and cleaning products. Non-aerosol cleaning products typically involve dabbing or soaking a rag with cleaning solution and then using the rag to wipe down surfaces or parts to remove contamination (U.S. EPA, 2014a). The cleaning solvent is usually applied in excess and allowed to air-dry (U.S. EPA, 2014a). Parts may be cleaned in place or removed from the service item for more thorough cleaning (U.S. EPA, 2014a).

***Aerosol Spray Degreasers and Cleaners***

Aerosol degreasing is a process that uses an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from fabricated parts. Products containing perchloroethylene may be used in aerosol degreasing applications such as brake cleaning, engine degreasing and metal product cleaning. This use has been previously described in EPA's 1-BP Draft Risk Assessment (U.S. EPA, 2016c). Aerosol degreasing may occur at either industrial facilities or at commercial repair shops to remove contaminants on items being serviced. Aerosol degreasing products may also be purchased and used by consumers for various applications.

### B.1.3.3 Lubricant and Greases

In the 2016 CDR (U.S. EPA, 2016b), two companies reported commercial use of perchloroethylene in lubricants and greases. The *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Tetrachloroethylene (Perchloroethylene)* [EPA-HQ-OPPT-2016-0732-0003 ] identified perchloroethylene in penetrating lubricants, cutting oils, aerosol lubricants, red greases, white lithium greases, silicone lubricants and greases and chain and cable lubricants. Most of the products identified by EPA are applied by either aerosol or non-aerosol spray applications.

### B.1.3.4 Adhesives and Sealants

Based on products identified in *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Tetrachloroethylene (Perchloroethylene)* [EPA-HQ-OPPT-2016-0732-0003 ] and 2016 CDR reporting, perchloroethylene may be used in adhesive and sealants for industrial, commercial and

consumer applications (U.S. EPA, 2016b). The OECD ESD for Use of Adhesives (2013) provides general process descriptions and worker activities for industrial adhesive uses.

Liquid adhesives are unloaded from containers into the coating reservoir, applied to a flat or three-dimensional substrate and the substrates are then joined and allowed to cure (OECD, 2013). The majority of adhesive applications include spray, roll, curtain, syringe or bead application (OECD, 2013). For solvent-based adhesives, the volatile solvent (in this case perchloroethylene) evaporates during the curing stage (OECD, 2013). Worker activities include unloading activities, container and equipment cleaning activities and manual applications of adhesive (OECD, 2013). Based on EPA's knowledge of the industry, overlap in process descriptions, worker activities and application methods are expected.

EPA's *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Tetrachloroethylene (Perchloroethylene)* (EPA-HQ-OPPT-2016-0732-0003) states that the use of perchloroethylene in consumer adhesives is especially prevalent with uses in arts and crafts and light repairs. EPA has also identified several sealants and adhesives that contain perchloroethylene and are marketed for commercial uses, such as construction applications. Based on EPA's knowledge of the industry, the likely application methods for commercial and consumer uses include spray, brush, syringe, eyedropper, roller and bead applications.

#### B.1.3.5 Paints and Coatings

Based on products identified in *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Tetrachloroethylene (Perchloroethylene)* (EPA-HQ-OPPT-2016-0732-0003) ] and 2016 CDR reporting (U.S. EPA, 2016b), perchloroethylene may be used in various paints and coatings for industrial, commercial and consumer applications. Several OECD ESDs and EPA generic scenarios provide general process descriptions and worker activities for industrial and commercial uses.

Typical coating applications include manual application with roller or brush, air spray systems, airless and air-assisted airless spray systems, electrostatic spray systems, electrodeposition/electrocoating and autodeposition, dip coating, curtain coating systems, roll coating systems and supercritical carbon dioxide systems (OECD, 2009c). After application, solvent-based coatings typically undergo a drying stage in which the solvent evaporates from the coating (OECD, 2009c).

#### B.1.3.6 Processing Aid for Pesticide, Fertilizer and Other Agricultural Manufacturing

In the 2016 CDR (U.S. EPA, 2016b), two sites owned by Olin Corporation reported use of perchloroethylene as a "processing aid, not otherwise listed" for use in the "pesticide, fertilizer, and other agricultural chemical manufacturing" industry.

#### B.1.3.7 Processing Aid, Specific to Petroleum Production

In the 2016 CDR (U.S. EPA, 2016b), two sites owned by Olin Corporation reported use of perchloroethylene as a "processing aid, specific to petroleum production" for use in the "Petrochemical Manufacturing" industry. A Dow Product Safety Assessment (Dow Chemical Co, 2008) for perchloroethylene describes a use at oil refineries for catalyst regeneration. EPA assumes this CDR reporting code is related to the use in catalyst regeneration.

#### B.1.3.8 Other Uses

***Other Industrial Uses***

Based on products identified in *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Tetrachloroethylene (Perchloroethylene)* (EPA-HQ-OPPT-2016-0732-0003) , a variety of other industrial uses may exist for perchloroethylene, including textile processing, laboratory applications, foundry applications and wood furniture manufacturing. It is unclear at this time the total volume of perchloroethylene used in any of these applications. More information on these uses will be gathered through expanded literature searches in subsequent phases of the risk evaluation process.

***Other Commercial/Consumer Uses***

Based on products identified in EPA's *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Tetrachloroethylene (Perchloroethylene)* (EPA-HQ-OPPT-2016-0732-0003) , a variety of other commercial and consumer uses may exist for perchloroethylene including carpet cleaning; laboratory applications; metal and stone polishes; inks and ink removal products; welding applications; photographic film applications; mold cleaning, release and protectant products. Similar to the "Other" industrial uses, more information on these uses will be gathered through expanded literature searches in subsequent phases of the risk evaluation process.

### B.1.4 Disposal

Perchloroethylene is listed as a hazardous waste under RCRA and federal regulations prevent land disposal of various chlorinated solvents that may contain perchloroethylene (ATSDR, 2014). Perchloroethylene may be disposed of by absorption in vermiculite, dry sand, earth or other similar material and then buried in a secured sanitary landfill or incineration (HSDB, 2012). In incineration, complete combustion is necessary to prevent phosgene formation and acid scrubbers must be used to remove any haloacids produced (ATSDR, 2014). Perchloroethylene may also be discharged to waterways if proper permits are held (ATSDR, 2014).

## B.2 Occupational Exposure Data

EPA presents below an example of occupational exposure-related information from the preliminary data gathering. EPA will consider this information and data in combination with other data and methods for use in the risk evaluation.

Table_Apx B- 1 summarizes OSHA CEHD data by NAICS code (OSHA, 2017).

**Table_Apx B- 1. Summary of Industry Sectors with Perchloroethylene Personal Monitoring Air Samples Obtained from OSHA Inspections Conducted Between 2011 and 2016**

| NAICS | NAICS Description |
|---|---|
| 236220 | Commercial and Institutional Building Construction |
| 238220 | Plumbing, Heating, and Air-Conditioning Contractors |
| 313310 | Textile and Fabric Finishing Mills |
| 313312 | Textile and Fabric Finishing (except Broadwoven Fabric) Mills |
| 323113 | Commercial Screen Printing |
| 326199 | All Other Plastics Product Manufacturing |
| 331512 | Steel Investment Foundries |
| 332439 | Other Metal Container Manufacturing |

| NAICS | NAICS Description |
|---|---|
| 332991 | Ball and Roller Bearing Manufacturing |
| 332996 | Fabricated Pipe and Pipe Fitting Manufacturing |
| 334511 | Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing |
| 335999 | All Other Miscellaneous Electrical Equipment and Component Manufacturing |
| 445110 | Supermarkets and Other Grocery (except Convenience) Stores |
| 448110 | Men's Clothing Stores |
| 485410 | School and Employee Bus Transportation |
| 811198 | All Other Automotive Repair and Maintenance |
| 812310 | Coin-Operated Laundries and Drycleaners |
| 812320 | Drycleaning and Laundry Services (except Coin-Operated) |
| 926150 | Regulation, Licensing, and Inspection of Miscellaneous Commercial Sectors |
| 927110 | Space Research and Technology |